UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

FWK HOLDINGS, LLC, MEIJER, INC., AND MEIJER DISTRIBUTION, INC., Plaintiffs, v. TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., AND PAR PHARMACEUTICAL, INC., Defendants.	C.A. No. 1:21-cv-11057-GAO
KPH HEALTHCARE SERVICES, INC., A/K/A KINNEY DRUGS, INC., Plaintiff, v. TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC, AND PAR PHARMACEUTICAL, INC., Defendants.	C.A. No. 1:21-cv-11255-GAO
IN RE AMITIZA ANTITRUST LITIGATION[1]	[Proposed] Lead Case No. 21-cv-11057-GAO

DIRECT PURCHASER CLASS PLAINTIFFS' CONSOLIDATED AMENDED CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

[1] On September 3, 2021, the parties filed a Revised Joint Stipulation and [Proposed] Order Regarding Service, the Filing of the Plaintiffs' Consolidated Complaint, and Motion to Dismiss Briefing Schedule (ECF Nos. 26 and 5, respectively), which included this proposed consolidated case caption.

The plaintiffs Meijer, Inc., Meijer Distribution, Inc., FWK Holdings, LLC, and KPH Healthcare Services, Inc., a/k/a. Kinney Drugs, Inc. (collectively, the "plaintiffs") bring this civil antitrust class action, on behalf of themselves and all others similarly situated, against Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and Par Pharmaceutical, Inc., based on personal knowledge as to themselves and upon information and belief as to all other allegations, and allege as follows.

I. INTRODUCTION

1. In September 2014, Takeda and its partner Sucampo, on the one hand, and Par, on the other, reached an anticompetitive agreement under which (1) Par agreed to delay launching a generic version of Takeda's Amitiza until January 1, 2021, (2) when Par eventually did launch, there would only be one generic in the market (whether Par's ANDA product alone or an authorized generic distributed by Par only), with the sides agreeing to split the generic revenue 50/50, and (3) Takeda/Sucampo agreed to prolong the one-generic-only artifice by keeping other generics out of the market for as long as they possibly could (the "Takeda/Sucampo-Par 2014 agreement").

2. The Takeda/Sucampo-Par 2014 agreement is only in part reflected in a September 30, 2014 written settlement document that also resolved some patent litigation. The settlement document reflects some of the anticompetitive terms, fails to disclose others, and in part is written to obscure the true anticompetitive effect of the overall Takeda/Sucampo-Par 2014 agreement.

3. For many years, Takeda, Sucampo, and Par concealed the anticompetitive aspects of their agreement. In the immediate wake of reaching their agreement, they concealed their agreement from the federal court presiding over the patent litigation, affirmatively misleading the court about how the arrangements were "procompetitive." They concealed the

anticompetitive aspects from the financial community, redacting critical pieces of the puzzle in their SEC filings.

4. In the absence of that anticompetitive agreement, there would have been at least two generics in the market as early as July 17, 2015, Par's ANDA product and Takeda's authorized generic, with other generic entry likely to follow.

5. This complaint seeks to recover overcharges paid by the direct purchaser class plaintiffs and the proposed direct purchaser class.

II. PARTIES

6. The plaintiffs Meijer, Inc. and Meijer Distribution, Inc., (collectively, "Meijer") are corporations organized under the laws of the state of Michigan, with their principal place of business located at 2929 Walker Avenue, NW, Grand Rapids, Michigan 49544. Meijer is the assignee of the claims of McKesson Corporation, which, during the class period, purchased brand and authorized generic Amitiza directly from Takeda and Par at supra-competitive prices and suffered antitrust injury as a result of the anticompetitive conduct alleged herein. Meijer purchased in each year from 2015 to the present.

7. Plaintiff FWK Holdings, LLC ("FWK") is a limited liability company organized under the laws of the state of Illinois, with its principal place of business located in Glen Ellyn, Illinois. FWK is the assignee of the claims of the Frank W. Kerr Company, which, during the class period, purchased brand Amitiza directly from Takeda at supra-competitive prices, and suffered antitrust injury as a result of the anticompetitive conduct alleged herein. Kerr purchased in 2015 and 2016 and thereafter went out of business.

8. Plaintiff KPH Healthcare Services, Inc., a/k/a. Kinney Drugs, Inc. ("KPH") is a corporation organized under the laws of the state of New York, with headquarters in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the

name Kinney Drugs, Inc. KPH is the assignee of the claims of McKesson Corporation, which, during the class period, purchased brand Amitiza directly from Takeda at supra-competitive prices and suffered antitrust injury as a result of the anticompetitive conduct alleged herein. KPH purchased generic Amitiza directly from Par during the class period at supra-competitive prices and therefore suffered antitrust injury as a result of the anticompetitive conduct alleged herein. KPH purchased in at least each year from 2015 through 2019 and in 2021.

9. Defendant Takeda Pharmaceutical Company Limited ("Takeda Japan") is a Japanese corporation having a principal place of business at 1-1, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo, Japan. Takeda Japan owns and controls Takeda Pharmaceuticals U.S.A., Inc., and was party to the unlawful settlement agreement with Par.

10. Defendant Takeda Pharmaceuticals U.S.A., Inc. ("Takeda U.S.A.," together with Takeda Japan, "Takeda") is a corporation jointly owned by Takeda Japan and another Takeda Japan subsidiary, non-party Takeda Pharmaceuticals International, AG. Takeda's principal place of business is at 95 Hayden Avenue, Lexington, Massachusetts 02421. As Takeda's website states: "Massachusetts serves as the U.S. hub for several global business operations, including the U.S. Commercial Business Unit, Global R&D, Global Oncology, Global Vaccines, Biologics Manufacturing and Cell Therapy Manufacturing." Takeda U.S.A. was party to the unlawful settlement agreement with Par and sold branded Amitiza in the United States and its territories during the class period.

11. Defendant Par Pharmaceutical, Inc. ("Par") is a New York corporation with its principal place of business in Chestnut Ridge, New York. Par is a subsidiary and operating company of Endo International plc ("Endo"). In September 2015, Endo completed an acquisition of Par Pharmaceuticals Holdings, Inc., and its subsidiaries, including Par, and

combined it with Endo's existing generics subsidiary, Qualitest Pharmaceuticals. Par was party to the unlawful settlement agreement with Takeda.

12. Non-defendant co-conspirator Sucampo Pharmaceuticals, Inc. ("Sucampo") was a Delaware corporation based in Bethesda, MD that co-developed and commercialized Amitiza with its partner Takeda. Sucampo was a party to many of the anticompetitive agreements alleged herein.

13. Non-defendant co-conspirator Mallinckrodt plc is an Irish public limited company that acquired Sucampo in February 2018 and took over its interests in Amitiza, including Sucampo's role in performing under the anticompetitive agreements alleged herein. Mallinckrodt filed for Chapter 11 bankruptcy in October 2020.

14. All of the defendants' and non-defendant co-conspirators' wrongful actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the defendants.

III. JURISDICTION AND VENUE

15. This action alleges violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, that are actionable under section 4 of the Clayton Act, 15 U.S.C. § 15(a). The action seeks to recover treble damages, interest, costs of suit, and reasonable attorneys' fees for the injuries sustained by the plaintiffs and members of the class resulting from the defendants' conspiracy to monopolize and to restrain trade in the United States market for Amitiza and its generic equivalents.

16. The Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1337(a) (antitrust), and 15 U.S.C. § 15 (Clayton Act).

17. Venue is appropriate within this district under 15 U.S.C. § 15(a), 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28 U.S.C. §1391(b) (general venue provision). The defendants transact business within this district and the defendants transact their affairs and carry out interstate trade and commerce, in substantial part, in this district. Further, the defendants and/or their agents may be found in this district.

18. The Court has personal jurisdiction over each defendant. Each defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY BACKGROUND

A. New Drug Applications and the listing of pharmaceutical patents in the FDA's Orange Book.

19. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"),[2] brand drug manufacturers that wish to sell a new drug product must obtain FDA approval by filing a New Drug Application ("NDA").[3] An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information about patents.[4]

20. The FDA may not approve an NDA if the data and test results provided fail to show that the drug is safe or if there is a lack of substantial evidence that the drug will be

[2] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. § 301 *et seq.*).

[3] 21 U.S.C. §§ 301–392.

[4] 21 U.S.C. § 355(a), (b).

effective to treat the conditions suggested in the proposed labeling. The FDA approves new drugs based on their ability to satisfy the minimum regulatory requirements—namely, show that they are safe and effective to treat a particular indication. New drug applicants are not required to, and usually do not try to, show that their new drug product is better than other similar, already approved, products.

21. When the FDA approves a brand manufacturer's NDA, the manufacturer may direct the FDA to list certain kinds of patents in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book")—i.e., patents that (1) cover the drug product, and (2) can "reasonably be asserted" against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents.[5] When a manufacturer obtains a new listable patent after the FDA has approved an NDA, it may direct FDA to list that patent in the Orange Book within 30 days of issuance.[6]

22. FDA's role in listing a patent in the Orange Book is ministerial.[7] The FDA does not make any attempt to verify the validity of a drug manufacturer's Orange Book listing. Instead, the agency relies on the brand manufacturer to truthfully represent its patents' validity and applicability. The purpose of centrally collecting and publishing this information is to provide generic companies and other drug applicants notice of which patents allegedly protect a particular drug.

23. As described further below (Section IV.D.2.), when a patent is (properly) listed in the Orange Book, a brand manufacturer may sue a generic company for infringing that patent

[5] Not all patents that may provide protection for an approved drug can be submitted for listing in the Orange Book. For example, patents covering processes for making a drug product do not satisfy the statutory requirements.

[6] 21 U.S.C. § 355(b)(1), (c)(2).

[7] *See, e.g.*, *In re Relafen Antitrust Litig.*, 360 F. Supp. 2d 166, 178 (D. Mass. 2005) (noting the "merely ministerial action" the FDA takes in listing a patent in the Orange Book).

before the generic product is sold. If it does, the FDA cannot approve the generic manufacturer's drug application for two-and-a-half years.

B. The typical patenting practices of brand drug companies.

24. Brand drug manufacturers frequently engage in a predictable pattern of developing patent portfolios for their profitable drugs.

25. The first patent or patents in a branded drug company's drug portfolio often reflect a bona fide technological advancement, i.e., the development of a new drug compound that provides a therapeutic benefit.

26. After the original patent applications are filed, the company will continue research and development efforts to create a drug product that will be approved by the FDA and, in turn, allow them to generate profits by selling the drug in the U.S. market.

27. As these research and development efforts continue, so do patent applications, which typically reflect narrower modifications relating to more specific formulations, processes for creating, and methods of using the original drug discovery. By this point, there is significant "prior art" by way of the earlier patent applications. These later patents are therefore increasingly limited in terms of the scope that they may actually cover. In other words, a brand company can patent new features or methods of using a drug, only so long as they are not obvious in light of, or anticipated by, the growing body of prior art.

28. By now the brand company may have submitted its NDA to the FDA for approval. Upon approval, or the likelihood of approval, and if the drug is projected to be a commercial success, the brand company will frequently ramp up its efforts to obtain additional patent protection. These later-applied-for-and-acquired patents frequently extend the ostensible period of patent exclusivity beyond the life of the original patents.

29. As a brand drug becomes a success, the incentive to obtain additional patent protection increases and brand drug manufacturers frequently intensify their efforts to do so. These patent applications typically result in patents (in light of the now extensive body of prior art) of still narrower coverage than the earlier-obtained patents. These narrower, later-obtained patents reflect, correspondingly, patents that are easier from the perspective of a would-be generic competitor to design or invent around by simply taking an approach that differs from those disclosed in the patents listed in the Orange Book by the brand drug manufacturer. They also often reflect claims directed to additional methods of using the drug that are either (1) not indications for which the FDA has approved the brand drug or (2) can be addressed by the generic "carving out" that use from its label (*see* Section IV.D.2.)—and so cannot lawfully prevent a generic competitor from coming to market.

C. The limits of patent protection for drugs.

30. The existence of one or more patents purporting to cover a drug product does not guarantee a brand drug company a monopoly over the drug. Patents are routinely invalidated or held unenforceable, either upon reexamination or *inter partes* proceedings by the U.S. Patent and Trademark Office ("PTO"), by court decision, or by jury verdict.

31. As discussed in greater detail below (Section IV.D.2.), under the framework set forth in the Hatch-Waxman Amendments, enacted in 1984,[8] a generic drug company can challenge patents ostensibly covering the branded drug. A patent infringement lawsuit by the patent holder within 45 days after notification of the generic drug company's challenge of the patents will trigger a 30-month stay of regulatory approval, during which the FDA cannot approve the generic drug.[9]

[8] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

[9] 21 U.S.C. § 355(j)(5)(B)(iii).

32. At all times, a patent holder bears the burden of proving infringement.

33. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

34. A patent is invalid or unenforceable when, e.g., (1) the disclosed invention is anticipated or obvious in light of earlier prior art; (2) when an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information known to that person to be material, or submits materially false information to the PTO during prosecution; and/or (3) when a later-acquired patent is not markedly distinct from the invention claimed in an earlier patent (and no exception, such as the safe harbor, applies).

35. In these circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of (1) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent; (2) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit; or (3) whether a patent may be "reasonably asserted" against a competitor or otherwise properly listed in the Orange Book.

36. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, *it is more likely that a challenged patent will be found invalid or not infringed than upheld.* The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002. An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly

reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.[10]

37. In Hatch-Waxman patent litigation, the parties are disputing whether the at-issue patent(s) are valid and enforceable, and manufacture or sale of the generic company's proposed generic product would actually infringe the brand's patent(s). Typically, the position of the brand is that the patent(s) is valid, enforceable and would be infringed, and that settlement should provide for entry at or near expiry of the patent. The position of the generic is that the patent(s) is invalid, unenforceable and/or not infringed, so a settlement should provide for immediate or near immediate entry. The strength of these positions can vary by generic depending, e.g., on how successful each generic has been at formulating its product so as to avoid infringing the brand's patents. A settlement on the merits—with a compromised agreed entry date and *without* a reverse payment or other undue influence on the generic's bargaining position—directly reflects the probabilistic outcome of the litigation. That is, the stronger the generic manufacturer's patent position, the earlier the entry date. The weaker the generic's patent position, the later the entry date.

38. If a generic manufacturer successfully defends against the brand's infringement lawsuit—either by showing that its proposed generic product does not infringe any asserted patents and/or that any asserted patents are invalid or unenforceable—the generic may enter the market immediately upon receiving approval from the FDA.

[10] John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1787 (2014) ("[P]atentees won only 164 of the 636 definitive merits rulings, or 26%," and "that number is essentially unchanged" from a decade ago.).

D. Congress eased the approval process for generic manufacturers, determining that—as a matter of good science—generic drug applicants need not conduct their own safety and efficacy studies.

39. A drug company that wants to sell a generic drug must file an Abbreviated New Drug Application ("ANDA") with the FDA.

40. To expedite the availability of affordable generic drugs, and as a matter of good science, Congress determined that generic drug manufacturers do not have to establish the safety and efficacy of the generic versions of brand drugs. Through the Hatch-Waxman Amendments, Congress reduced the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.

41. Instead, an ANDA applicant must show that the drug product described in the ANDA is "the same as" the brand drug.[11] That is, that the generic product contains the same active ingredient, conditions of use, route of administration, dosage form, strength, rate and extent of absorption (bioequivalence), and—with certain permissible differences—labeling as the reference listed drug.[12] Having done so, the ANDA applicant may rely on the FDA's previous finding that the brand drug product is safe and effective because—as a matter of good science and decades of experience—there is no reason to believe that the generic product would behave differently in the body than the brand product. If a generic application meets those criteria relative to its brand counterpart, the FDA assigns the generic drug an "AB" rating.

42. Upon receipt of the ANDA for filing by the FDA, meaning that the "FDA has made a threshold determination that the abbreviated application is substantially complete,"[13]

[11] *See* 21 U.S.C. § 355(j)(2)(A) (2008) (the same conditions of use, active ingredient(s), route of administration, dosage form, strength, rate and extent of absorption (bioequivalence), and labeling).

[12] *Id.* § 355(j)(2)(A)(iv); *see also* 21 C.F.R. 314.94(a)(7).

[13] 21 C.F.R. § 314.101(b)(1).

the agency must review the ANDA, including the data and other information in it purporting to support bioequivalence, and determine whether it meets the requirements for approval.[14]

1. An ANDA applicant must establish bioequivalence: that the rate and extent of the absorption at the site of action is not significantly different from the brand drug.

43. An ANDA applicant must demonstrate that its proposed generic drug is bioequivalent to the reference listed drug.[15] A generic drug is bioequivalent to the listed drug if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses."[16]

44. A showing that the active ingredient in the proposed generic drug reaches the site of drug action at a rate and to an extent not significantly different from that of the reference listed drug (along with other information required for approval) permits the FDA to conclude that the proposed generic drug can be expected to perform the same way in the body as the reference listed drug.

45. Bioequivalence testing determines whether differences in formulation (e.g., differences in inactive ingredients) between a proposed generic drug and the reference listed drug have an impact on the rate and extent to which the active ingredient becomes available at the site of action. The statute, regulations, and case law give the FDA considerable flexibility in determining how the bioequivalence requirement is met.

---

[14] *See* 21 C.F.R. § 314.100(a).

[15] *See, e.g.*, 21 U.S.C. § 355(j)(2)(A)(iv) (requiring "information to show that the new drug is bioequivalent to the listed drug"); 21 C.F.R. 314.94(a)(7) (requiring, as part of ANDA content and format, information to show that the drug product is bioequivalent to the reference listed drug); 21 C.F.R. 314.127(a)(6)(i) (providing that FDA will refuse to approve an ANDA if information submitted is insufficient to show that the drug product is bioequivalent to the reference listed drug referred to in the ANDA).

[16] 21 U.S.C. § 355(j)(8)(B)(i); *see also* 21 C.F.R. § 320.23(b).

46. The FDA has repeatedly debunked the myth that the 80–125% variance permitted means that, e.g., a generic drug could contain 40% more (or less) of the active ingredient than the brand, including in the Orange Book.

47. Clinical end point studies are one of the least preferred, and least reliable, methods of showing bioequivalence and may result in unnecessary human research.[17]

48. Congress intended to grant the FDA wide discretion to establish bioequivalence standards on a drug-by-drug basis when it enacted the Hatch-Waxman Amendments. The FDA is permitted to use the latest scientific advances in approving drug products.[18] And the courts have recognized the FDA's discretion to determine how the bioequivalence requirement should be met for a product or class of products, so long as the FDA's determination is not contrary to the governing statute and regulations and is based on a "reasonable and scientifically supported criterion."[19] Courts that have considered the FDA's bioequivalence determinations have consistently upheld the aspects of the FDA's implementation of the FDCA's bioequivalence requirements at issue in those cases.[20]

2. FDA sometimes, after considering the matter in detail, provides guidance documents suggesting how bioequivalence may be shown for a particular drug product.

49. The FDA periodically publishes notices in the Federal Register announcing the availability of draft, revised draft, and final versions of product-specific bioequivalence

[17] 21 C.F.R. § 320.24(b); 21 C.F.R. § 320.25(a) (stating that a "guiding principle" for the conduct of an in vivo bioavailability study is that "that no unnecessary human research should be done"); Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,883 (July 10, 1989) (in discussing § 320.22, the FDA clarified that it "does not believe Congress intended that unnecessary human research be conducted . . . if the agency concludes that bioequivalence can be demonstrated by in vitro tests, the agency proposes to require only such tests rather than in vivo studies").

[18] Bioavailability and Bioequivalence Requirements: Procedures for Establishing a Bioequivalence Requirement, 42 Fed. Reg. 1,624, 1,629 (Jan. 7, 1977) ("As with all new regulations relating to an evolving science, the Commissioner reserves the right to consider other factors that may indicate the need to establish a bioequivalence requirement.").

[19] *Schering*, 782 F. Supp. at 651; *see also Fisons*, 860 F. Supp. at 866–67 ("[T]he factual determination of how bioequivalence is determined properly rests within the FDA's discretion.").

[20] *See, e.g.*, *Schering*, 782 F. Supp. at 650–51; *Fisons*, 860 F. Supp. at 866–87.

recommendations. These notices identify a comment period for draft bioequivalence recommendations and instructions as to how to submit comments through the proper channels.[21]

50. The FDA considers comments received on product-specific bioequivalence recommendations in developing its recommendations. As with FDA guidance in general, these recommendations describe the FDA's "current thinking" and should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. Applicants following product-specific bioequivalence recommendations have an expectation that the FDA will agree that their approach to establishing bioequivalence is appropriate.[22] However, applicants may confer with the agency on use of different approaches for establishing bioequivalence.

51. FDA does not always finalize guidances.[23] Many sit in draft form forever. Finalizing guidances can be a time-consuming process that would be expected to extend the time involved if the petition were to be granted.

52. Recommendations made in a draft or final guidance does not bind the FDA or the public. Further, even in the absence of product-specific bioequivalence guidance, the FDA has the authority to approve a product supported by bioequivalence data that meets the statutory and regulatory requirements.

---

[21] 21 C.F.R. § 10.115(d)(3) ("Although [final] guidance documents do not legally bind FDA, they represent the Agency's current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence.").

[22] *Id.*

[23] *See, e.g.*, FDA's Denial of GlaxoSmithKline's Citizen Petitions Concerning Flonase, at 21 (Feb. 22, 2006) ("Neither the Act nor FDA regulations require FDA to issue final guidance prior to approving an ANDA. As in the new drug approval process, FDA is required to make decisions based on the information provided by individual applicants and evaluate the scientific content of ANDAs to determine if the application meets the statutory and regulatory requirements."; "Whether or not FDA issues a final guidance does not speak to the scientific validity of FDA's bioequivalence methodology.").

3. The FDA's longstanding practice is to approve one or more ANDAs on the same day that it denies a citizen petition challenging bioequivalence standards.

53. Section 505(j) of the FDCA creates a mechanism through which a person may file a petition with the FDA requesting the agency take, or refrain from taking, any form of administrative action. This mechanism is commonly referred to as a "citizen petition." These petitions, when used as intended, provide an opportunity for individuals to express their genuine concerns about safety, scientific, or legal issues regarding a product before, or after, its market entry.

54. There are many other ways for interested parties to make their views known to the FDA on bioequivalence topics. They may participate in advisory committee meetings, respond to requests for comments on draft of final guidance, etc. When brand companies choose to file citizen petitions, they are choosing a vehicle that is inherently disruptive to the FDA's ongoing generic drug review and approval functions.

55. The filing of a citizen petition that challenges bioequivalence standards imposes a burden on the FDA. Reviewing and responding to citizen petitions is a resource-intensive and time-consuming task. The FDA must research the petition's subject and examine scientific, medical, legal, and sometimes economic issues. The FDA must also coordinate internal agency review and clearance of the petition response. These activities strain the FDA's limited resources.

56. The FDA regularly approves one or more ANDAs on the same day that it denies a brand companies' citizen petition asking that it not approve generics unless they meet onerous proposed bioequivalence requirements (that often exceed what is contemplated/permitted by the ANDA regulatory framework)—clearing the way for competition to begin. This is well known in the industry.

57. And, as discussed further below, it is FDA's longtime practice to pay attention to target dates, including expirations of the 30-month stay, and prioritizes its resources to do what it can to get one or more generics on the market as soon as possible.[24]

E. An ANDA applicant must address the brand's patents, either through a Paragraph IV challenge, a Section viii carve-out, or other means.

58. Section 505(j)(2)(A)(i) of the Act requires that an ANDA contain "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a [listed drug]." This language reflects Congress's intent that the generic drug be safe and effective for each "condition of use" prescribed, recommended, or suggested in the generic drug labeling. But it does not require that an ANDA be approved for each condition of use for which the reference listed drug is approved. Thus, in § 314.92(a)(l), the FDA has explicitly stated that a proposed generic drug product must have the same conditions of use as the listed drug, "except that conditions of use for which approval cannot be granted because of . . . an existing patent may be omitted" (emphasis added).[25]

[24] The abuse of the citizen petition process led Congress to add § 505(q) to the FDCA in 2007 through the FDA Amendments Act (the "FDAAA") to try to curb citizen petition abuses. 21 U.S.C. § 355(q). But in a 2012 report to Congress, the FDA stated that it was "concerned that section 505(q) may not be discouraging the submissions of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive drug products." Food & Drug Admin., *Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2011* (Dec. 14, 2012). Indeed, recent studies have found that many petitions from brand drug manufacturers "appear to be last-ditch efforts to hold off generic competition," Robin Feldman et al., *Empirical Evidence of Drug Pricing Games—A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39, 70 (2017), and that between 2011 and 2015, the FDA denied 92% of § 505(q) citizen petitions, Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305, 338, 339 tbl. 8 (2016).

[25] The Act also requires that an ANDA contain "information to show that the labeling proposed for the new [generic] drug is the same as the labeling approved for the listed drug. . . except for changes required because of differences approved under a petition filed under [section 505(j)(2)(C) of the Act] or because the new drug and the listed drug are produced or distributed by different manufacturers" (section 505(j)(2)(A)(v) of the Act). A parallel provision appears in section 505(j)(4)(G) of the Act—providing that the FDA must approve an ANDA unless, among other things, the "information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for [the reference listed drug] except for changes required because of differences approved under [an ANDA suitability petition] or because the drug and the listed drug are produced or distributed by different manufacturers."

59. To obtain FDA approval of its ANDA, a generic manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. There are two basic approaches to certification.

60. First, under Section 505(j)(2)(A)(viii) of the Act, the generic manufacturer may issue a "section viii" statement, providing that it will market the generic drug only for methods of use that are not covered by the brand drug's patents, i.e., it will "carve out" the patent-protected methods of use and related labeling from its ANDA product.

61. A section viii statement is commonly used when the patent on the brand drug compound has expired and the only patents remaining relate to some approved methods of using the drug. The ANDA applicant then proposes labeling for the generic drug that "carves out" from the brand's approved label the still-patented methods of use.[26] The FDA may then approve the modified label under § 314.127(a)(7).[27]

62. FDA regulations expressly recognize that by submitting a section viii statement, an ANDA applicant may omit from the proposed labeling a method of use protected by a listed patent, and therefore need not seek approval for that use.[28]

63. Second, under paragraphs I through IV of Section 505(j)(2)(A)(VI) of the Act, a generic manufacturer may contain one of four certifications:

---

[26] The FDCA allows a generic product to have a different drug label than the brand that relate to "[D]ifferences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, *or omission of an indication or other aspect of labeling protected by patent* or accorded exclusivity under section 505(j)(5)(F) of the [A]ct." 21 C.F.R. § 314.94(a)(8)(iv) (emphasis added).

[27] *See Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012) (citing 21 C.F.R. 314.94(a)(8)(iv)).

[28] *See also* the final rule, Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed (68 Fed. Reg. 36,676 (June 18, 2003)). In the preamble to this final rule, FDA stated that the section viii statement permits an ANDA applicant to "avoid certifying to a patent by stating that it is not seeking approval for the use claimed in the listed patent" (68 Fed. Reg. 36,676, 36,682). FDA stated, "[o]ur position has been that, for an ANDA applicant to file a Section viii statement, it must 'carve-out' from the proposed ANDA labeling, the labeling protected by the listed patent" (*id.*).

> That no patent for the brand has been filed with the FDA (a "paragraph I certification");
>
> That any patent(s) for the brand has/have expired (a "paragraph II certification");
>
> That any patent(s) for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a "paragraph III certification"); or
>
> That any patent(s) for the brand is/are invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").[29]

64. If an applicant files a paragraph I or II certification, the patent in question will not delay ANDA approval. If an applicant files a paragraph III certification, the applicant agrees to wait until the relevant patent has expired before seeking full effective approval of its ANDA.

65. Once the FDA informs the ANDA filer that its ANDA is sufficiently complete to review, the ANDA filer must notify the NDA holder. Paragraph IV notifications are required by law to provide "a detailed statement of the factual and legal basis of the opinion of the applicant" that the challenged patents would not be infringed by the manufacture, use or sale of the ANDA product.[30]

66. If a generic manufacturer files a paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer files suit against the generic filer within 45 days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA-filer (which would enable the manufacturer to market and sell its product) until the earlier of (1) the passage of two and a half years (thirty months), or (2) the issuance of a decision by a court that the patent at issue is invalid or not infringed by the generic

[29] 21 U.S.C. § 355(j)(2)(A)(vii).

[30] 21 U.S.C. § 355(j)(2)(B).

manufacturer's ANDA. Until one of those conditions occurs, the FDA may only grant "tentative approval," but cannot authorize the generic manufacturer to market its product (i.e., grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA meets all regulatory requirements and is ready for final approval but for the 30-month stay.

F. The first ANDA applicant to submit a Paragraph IV certification challenging the brand's patent(s) may be entitled to 180-days as the only approved ANDA product on the market.

67. To encourage manufacturers to challenge patents and seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first paragraph IV generic manufacturer ANDA filer ("first-filer") a 180-day exclusivity period to market the generic version of the drug; the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug during that time.[31] That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand are either invalid or not infringed by the generic, in most circumstances the FDA cannot approve a later generic manufacturer's ANDA until that first-filer generic(s) has been on the market for 180 days.[32]

68. The first-filer may, or may not, earn 180 days (six months) as the only ANDA product available. "This period of exclusivity is the most profitable time for a new generic drug

[31] 21 U.S.C. § 355(j)(5)(B)(iv), (D). A first-filer who informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing generics.

[32] There is an exception: if the first-filer forfeits exclusivity. A first-filer can forfeit its 180-day exclusivity by, for example, failing to obtain tentative approval from the FDA for its ANDA within 30 months of filing its ANDA.

because the first filer typically procures an overwhelming majority of the sales of the drug while offering only a modest discount off the brand drug price."[33]

69. While the 180-day window is often referred to as the first-filer's six-month or 180-day "exclusivity," that term is a bit of a misnomer because the brand manufacturer can launch an authorized generic (sometimes referred as an "AG") at any time, manufacturing its AG in accordance with its approved NDA for the branded product, but without the brand drug name on the product, and selling at a lower price point.

70. To be eligible for the 180-day first-filer exclusivity, an ANDA applicant must (1) file the first substantially complete ANDA; (2) challenge the brand's patent(s); and (3) obtain tentative approval within 30 months (two and a half years) of filing—a "deadline" that "motivate[s] prospects to get to market sooner" and which may be "extended" if a change in the requirements causes the ANDA filer to miss the deadline.[34]

71. The FDA grants "tentative approval" to an ANDA that meets the conditions of approval and is ineligible for final approval because of an unexpired exclusivity or stay.

72. If a first-filer does not obtain tentative approval within 30 months of filing its ANDA (with one exception), it forfeits its 180-day exclusivity.[35] The exclusivity evaporates; it does not pass along to the next generic in line,[36] though "exclusivity" is a bit of a misnomer, as the brand can launch an authorized generic at any time.

---

[33] *In re Ranbaxy Generic Drug Application Antitrust Litig.*, No. 19-md-02878-NMG, 2019 WL 6341298, at *2 (D. Mass. Nov. 27, 2019), *motion to certify appeal denied*, No. 19-md-02878-NMG, 2020 WL 759369 (D. Mass. Feb. 14, 2020).

[34] *See Meijer, Inc. v. Ranbaxy Inc.*, No. 15-cv-11828-NMG, 2016 WL 4697331, at *3 (D. Mass. June 16, 2016), report and recommendation adopted (Sept. 7, 2016); 21 U.S.C. § 355(j)(5)(D)(i)(IV); *see also* 21 U.S.C. § 55(j)(5)(D)(iii) ("If all first applicants forfeit the 180-day exclusivity period under clause (ii) . . . (II) no applicant shall be eligible for a 180-day exclusivity period"). An ANDA filer must also avoid triggering forfeiture.

[35] 21 U.S.C. § 355(j)(5)(D)(i)(IV).

[36] Food & Drug Admin., *Guidance for Industry, 180-Day Exclusivity: Questions and Answers*, at 6 (draft Jan. 2017), *available at* https://www.fda.gov/media/102650/download.

73. For later-filed ANDAs, meaning not first-filed ANDAs, tentative approval is not required. The FDA may award final approval to a generic manufacturer's later-filed ANDA without taking the intermediate step of granting tentative approval.[37]

G. The FDA appreciates target dates and prioritizes getting the first generic to market.

74. The FDA has long prioritized the review of ANDAs for a first generic product; it does so with the goal of enabling the first-filer to get to market as soon as possible, i.e., when blocking patents or exclusivities have expired or otherwise have been addressed. FDA is mindful of key dates, including expiration of 30-month stays, and prioritizes review of ANDAs with the goal of approving a generic product before or on those dates.[38]

V. ECONOMIC BACKGROUND

A. AB-rated generic competition dramatically lowers the price of the drug.

75. Again, generic and authorized generic versions of brand name pharmaceutical drugs contain the same active ingredient(s) as the brand name drug and are determined by the FDA to be bioequivalent to the brand and, therefore, just as safe and effective as their brand counterparts. The only material difference between generics and their corresponding brand versions is the price.

---

[37] Rebuttal Expert Report of Jon Clark ¶ 33.

[38] *See, e.g.*, Review Order of Original ANDAs, Amendments and Supplements, CDER Manual of Policies and Procedures (MAPP) 5240.3, at 3 (Oct. 18, 2006) ("If the application relates to a product that is . . . a first generic product for which there are no blocking patents or exclusivities, and the Director of the Office of Generic Drugs has authorized expedited review in writing, the application will be placed at the head of the review queue for the appropriate team."); Prioritization of the Review of Original ANDAs, Amendments, and Supplements, CDER MAPP 5240.3, at 3 (Rev. 1, Aug. 1, 2014) ("Submissions that contain a Paragraph IV certification, but become eligible for approval during the review period as a result of no blocking patents or exclusivities (including 180-day exclusivity) and no applicable stays, may receive expedited review if no other generic version of the same reference listed drug (RLD) has yet been brought to market under an approved ANDA."); Food & Drug Admin., Generic Drug User Fee Act Program Performance Goals and Procedures—Commitment Letter at 6-7 (Jan. 12, 2012) (FDA will expedite review of first-filed ANDAs and "those applications that become eligible for approval during the review period as a result of no blocking exclusivities, patent(s) and/or applicable stays based on appropriate documentation submitted."), *available at* https://www.fda.gov/media/82022/download.

76. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a branded product and its generic version, or between generic versions, is price.

77. The first generic on the market typically enters at a price slightly lower than the brand price and captures most of the market. As additional generics enter, price competition between generics reduces the price substantially, and causes the generics to take over even more market share from the brand. Typically, when there is only one generic competitor, it will price at 10% less expensive than the brand counterpart, while two generic competitors will price at a 40% discount (or more) from the brand price within months of entry, and with three or more generic competitors, the generic price will decline even further. Consequently, the launch of a first generic or of additional generics usually results in significant cost savings for all drug purchasers, especially direct purchasers.

78. Since the passage of the Hatch-Waxman Amendments, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is not permitted). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic where the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic enters the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market within the first six months. A 2010 study conducted by the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple

generics on the market) prices had dropped 85%.[39] These price declines and generic penetration rates have increased since 2010.

79. As a result, generic competition is viewed by brand manufacturers like Takeda as a grave threat to their bottom lines. In its public filings, for example, Takeda Japan warns investors that "[t]he loss of market exclusivity for pharmaceutical products opens such products to competition from generic substitutes that are typically priced significantly lower than the original products, which typically adversely affects the market share and prices of the original products . . . The introduction of generic versions of a pharmaceutical product typically leads to a swift and substantial decline in the sales of the original product."[40]

80. Without competition, a brand manufacturer keeps all profit from sales of the drug. When generics enter, competition converts the brand's profits into purchaser savings.

81. Generic competition enables all direct purchasers of a drug to (1) purchase generic versions of the drug at substantially lower prices, and/or (2) purchase the brand at a reduced price.

82. Until a generic version of the brand drug enters the market, however, there is no bioequivalent drug to substitute for and compete with the brand, and the brand manufacturer can therefore continue to profitably charge supra-competitive prices.

83. Once generics enter the market, the brand manufacturer's sales decline to a small fraction of their level before generic entry. This is because, "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs

[39] *See* FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), *available at* https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf ("FTC Pay-for-Delay Study").

[40] Takeda Pharmaceutical Company Limited, Annual Report (Form 20-F), at 9 (June 29, 2021), *available at* https://www.sec.gov/ix?doc=/Archives/edgar/data/1395064/000139506421000140/tak-20210331.htm.

save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[41]

B. Brand companies compete on price with generics by marketing authorized generic versions of their branded drugs.

84. Brand manufacturers, like Takeda, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible—including illegal means—to delay or prevent generic competition.

85. Nothing prevents a brand manufacturer from marketing and selling an authorized generic ("AG") at any time. An AG is chemically identical to the brand drug but sold as a generic—typically through either the brand manufacturer's generic distribution subsidiary (if it has one) or through a third-party distributor. An AG is essentially the brand product in a different package. A brand manufacturer need not file an ANDA, or obtain any additional FDA approvals,[42] to market its authorized generic (or to license the AG to a third party for marketing and sale).

86. A first-filer's 180-day exclusivity period only applies to other generic companies, and it does not block the brand drug manufacturer from selling an AG during that period.

87. The FDA has found that allowing brand manufacturers to introduce AGs during the 180-day exclusivity period is consistent with the "fundamental objective of the Hatch-Waxman amendments," to encourage competition and, as a result, "lower prices in the pharmaceutical market."[43] The FDA reasoned that if a brand releases an AG at a reduced price

[41] https://www.fda.gov/drugs/generic-drugs/what-are-generic-drugs.

[42] An authorized generic requires a different national drug code than the branded drug, which can be obtained by simple request to the FDA. *See* 21 C.F.R. § 207.35.

[43] Food & Drug Admin., Decision Denying Citizen Petitions of Teva and Mylan, Dkt. Nos. 2004P-0075/CP1 & 2004P-0261/CP1, at 11–12 (July 2, 2004).

during the 180-day exclusivity period, "this might reasonably be expected to diminish the economic benefit" to the generic first-filer by increasing competition and causing the generic to "reduc[e] the substantial 'mark-up' [generics] can often apply during the [180-day] period . . . ."[44] Such competition, and the resulting price decreases, work to benefit drug purchasers.

88. Brand manufacturers, like Takeda and Sucampo, recognize the significant economic advantages of releasing their AGs during the 180-day exclusivity period. One study notes that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[45]

89. Brand manufacturers can produce the AG at low cost and low risk, since AGs do not require FDA approval or additional R&D, and the brand already has the technical ability to manufacture the product.

90. Brand manufacturers can use the AG to retain some of the market share, revenue, and profit that they would otherwise lose to the first-filer generic during its 180 days of exclusivity.

91. Competition from an AG substantially reduces drug prices and the revenues of the first-filer generic (especially during the 180-day exclusivity period).

92. A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[46]

---

[44] *Id.* at 12.

[45] Kevin A. Hassett & Robert J. Shapiro, Sonecon, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals* 3 (2007), *available at* http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf.

[46] Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 HEALTH AFFAIRS 790, 796 (2007).

93. The FTC similarly found in a 2011 report that AGs capture a significant portion of sales, reducing the first-filer generic's revenues by about 50% on average.[47] These reductions too have increased since 2011. The first-filer generic makes much less money when it faces competition from an AG because (1) the AG takes a large share of unit sales away from the first-filer, and (2) the presence of the AG causes prices, particularly generic prices, to decrease.

94. Authorized generics are therefore a significant source of price competition when they result in multi-source generics (meaning, more than one generic on the market). In fact, they are the only potential source of generic price competition during the first-to-file generic manufacturer's 180-day exclusivity period. All drug industry participants recognize this. PhRma recognizes it.[48] Generic companies recognize it.[49] Brand companies recognize it.[50]

---

[47] FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, 139 (2011), available at https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("FTC 2011 AG Study").

[48] Brand industry group PhRma sponsored a study that concludes that the presence of an authorized generic causes generic prices to be more than 15% lower as compared to when there is no authorized generic. IMS Consulting, *Assessment of Authorized Generics in the U.S.* (2006), *available at* http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf.

[49] One generic stated that "[d]ue to market share and pricing erosion at the hands of the authorized [generic], we estimate that the profits for the 'pure' generic during the exclusivity period could be reduced by approximately 60% in a typical scenario." *See* FTC 2011 AG Study at 81. Another generic manufacturer quantified the fiscal consequences of competing with an authorized generic and determined that the authorized generic reduced its first generic's revenues by *two-thirds*, or by approximately *$400 million*. Comment of Apotex Corp. in Support of Mylan Citizen Petition at 4, Docket No. 2004P–0075 (Mar. 24, 2004), *available at* https://web.archive.org/web/20041216115511/http://www.fda.gov/ohrms/dockets/dailys/04/apr04/040204/04P-0075-emc00001.pdf.

[50] Commenting on an FDA petition by drug manufacturer Teva Pharmaceuticals, Pfizer stated: "Teva's petition [to prevent the launch of an authorized generic] is a *flagrant effort to stifle price competition* – to Teva's benefit and the public's detriment." Comment of Pfizer at 6-7, Docket No. 2004P-0261 (June 23, 2004), *available at* https://web.archive.org/web/20050601041653/http://www.fda.gov/ohrms/dockets/dailys/04/June04/062904/04p-0261-cr00001-01-vol2.pdf; Comment of Johnson & Johnson at 1, FDA Docket No. 2004P-0075 (May 11, 2004), *available at* https://web.archive.org/web/20041227172543/http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00002-vol1.pdf.

VI. ABUSE OF THE REGULATORY STRUCTURE BY DRUG COMPANIES

A. The incentive to challenge patents and obtain 180-day exclusivity can be manipulated to create a bottleneck in competition.

95. The brand manufacturer of a pharmaceutical product that has no generic competition in the marketplace gets all of the profits on all of the unit sales. In this circumstance, brand manufacturers can usually sell their drug for far more than the marginal cost of production, generating profit margins in excess of 70% while making hundreds of millions of dollars in sales. The ability to make those kinds of profit margins is what economists call market power.

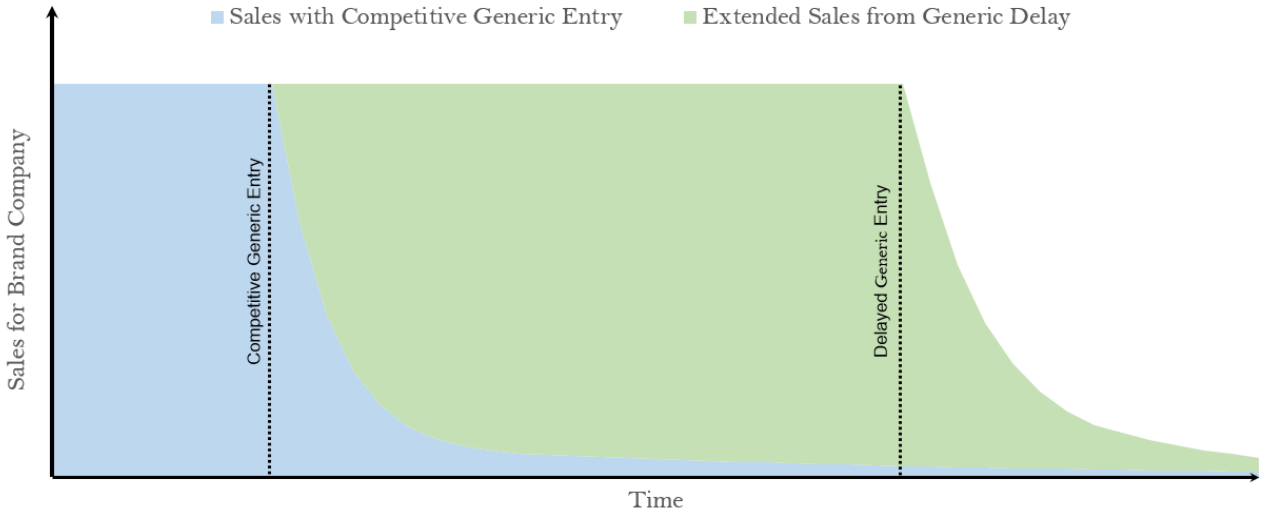
96. When a generic equivalent enters the market, however, it quickly captures 80% or more of the unit sales from the brand drug. When generic entry occurs, the brand manufacturer loses most of the unit sales and the generic manufacturer sells most of the units, but at drastically reduced prices—delivering enormous savings to drug purchasers. And when multiple generics compete in the market, that competition drives prices down to near the marginal cost of production. This competition ends the brand manufacturer's market power and delivers enormous savings to drug purchasers. Competition converts what formerly were excess profits into purchaser savings.

97. While brand manufacturers and first-filer generic manufacturers are typically marketplace competitors, they have a collective interest in preventing robust competition from several generic manufacturers—competition that severely depresses prices—from breaking out. If they work together to prevent or delay such competition, they can keep prices and profit margins on all of the unit sales higher and split the resulting excess profits among themselves. In other words, by stifling competition, the brand manufacturer and first-filer generic manufacturer can maintain high prices, protect their profits, and split between themselves the

enormous savings that increased generic competition would have delivered to drug purchasers, such as the plaintiffs.

98. Figure 1 compares the impact on a brand manufacturer's profits between (1) a situation where it settles a patent lawsuit on the merits (i.e., with only an agreed entry date and without a pay-off to the generic company); and (2) a situation where it settles the lawsuit with a large, unjustified payment to the generic manufacturer. In the former situation, the agreed entry date for the generic is earlier and the brand manufacturer's profits are thus greatly reduced. In the latter situation, the agreed entry date is later and the brand manufacturer's profits increase significantly. Earlier entry may also occur if the generic manufacturer launches its product at risk (i.e., while the litigation is still pending) or prevails in the patent litigation and then launches its product.

Figure 1: Effect of Delayed Entry on Sales



99. For such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide between them the ill-gotten gains—the increased profit to the detriment of drug purchasers—that delayed competition makes possible. The means usually

takes the form of payoffs from the brand manufacturer, deals that are often referred to as "pay-for-delay," "exclusion payment," or "reverse payment" agreements.

100. The brand manufacturer may choose to—unlawfully—pay off only the first-filer, even if other generic manufacturers are also lined up to challenge the patents. The first-filer's agreement to delay marketing its generic drug also prevents other generic manufacturers from marketing their products: none of the later-filers can enter until the first-filer's 180-day exclusivity period has ended.

101. Later ANDA filers have more modest financial expectations because they may have little or no expectation of any form of market exclusivity. By the time they enter the market, there is at least the brand and one other generic on the market (and often a second generic in the form of an AG) and, thus, the drug has already been, or is on its way to being, commoditized.

102. But the decision to pay-off only the first-filer nonetheless has detrimental effects on competition. In the absence of an anticompetitive agreement between the brand company and the first-filer, later ANDA filers have procompetitive incentives. They are motivated to expend resources to challenge the brand manufacturer's patent(s) (knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

103. When an anticompetitive agreement with the first-filer is already in place, however, pursuing the litigation to conclusion becomes less attractive to later filers. The later generic manufacturers know that the first-filer is not leading the charge against the brand manufacturer's patent(s) (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive reverse payment agreement). The later generics will therefore have to bear the full brunt of the litigation costs themselves, and, upon prevailing in the patent litigation, can expect to recoup less of those costs than the first-filers would have

enjoyed, because the later-filers will face more robust generic competition than a first-filer who enjoys an exclusivity period.

104. Thus, some later generics decide to simply give in to or join the conspiracy between the brand manufacturer and the first-filer generic, agree to drop their challenges to the brand manufacturer's patent(s), and stay off the market until after entry by the first-filer. This behavior furthers the harm to drug purchasers.

105. Pay-for-delay agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly by blocking access to more affordable generic drugs, forcing purchasers to buy expensive brands instead.

B. Reverse payments are a means to delay competition.

106. In connection with the resolution of patent litigation arising out of paragraph IV certifications, brand manufacturers sometimes unlawfully pay off generic competitors in exchange for delaying their entry into the market. These agreements not to compete are known as "reverse payment agreements" or "pay-for-delay agreements."

107. In a typical reverse payment agreement, the brand manufacturer pays a generic manufacturer to (1) delay or abandon market entry, and (2) abandon the invalidity and unenforceability challenges to the brand manufacturer's patents. The brand manufacturer preserves its monopoly by paying some of its monopoly profits to the generic manufacturer, and the generic manufacturer agrees to delay marketing its product, allowing the brand manufacturer to have an extended monopoly period.

108. The size of the payment is usually a proxy for assessing the patent merits. As the Supreme Court observed in *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 157–58 (2013), "[t]he owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity

justifies a large payment. But be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition." In other words, the Court went on, "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness . . . ."

109. In the 1990s, these agreements took the form of cash payments from the brand manufacturer to the generic competitor. As a result of regulatory scrutiny, congressional investigations, and class-action lawsuits, brand manufacturers and generic competitors have entered into increasingly elaborate agreements in attempts to hide the fundamentally anticompetitive character of these agreements and avoid liability.

1. No-authorized generic agreements provide a means for brand and generic manufacturers to share the gains from conspiring.

110. One form of payoff, at issue here and which brand companies have increasingly used to disguise their reverse payments, is a "no-authorized generic." With a no-authorized generic agreement, the brand manufacturer agrees not to market an AG version of the brand drug—or structures the settlement so that it would make no economic sense for the brand to launch an AG (i.e., a de facto no-AG agreement)—for some period of time after the first generic enters the market, in exchange for the first generic agreeing to a delayed entry date.

111. There is no statutory prohibition on a brand manufacturer launching an AG during the first-filer's 180-day ANDA exclusivity period. The Hatch-Waxman amendments' 180-day marketing period is "exclusive" only against other ANDA-based products, not as against the brand manufacturer's NDA-based AG.

112. Absent a no-authorized generic promise, it almost always makes economic sense for the brand manufacturer to begin marketing an AG as soon as (or sometimes weeks or months before) the first generic enters the marketplace.

113. But competition from an AG has a drastically negative effect on the first-filer generic's revenues. Competition from an AG typically cuts the first-filer's revenues by more

than half, as the competing generic takes a substantial volume of the unit sales and drives prices lower—delivering commensurate savings to drug purchasers.

114. To prevent an AG from causing this substantial loss of revenues and profits, a first-filer generic may be willing to delay its entry into the marketplace in return for the brand manufacturer's agreement to forgo competing with an AG during the exclusivity period. The additional monopoly profits that the brand manufacturer gains from the delayed onset of generic competition more than makes up for the profits it forgoes by temporarily not competing with its AG. The brand manufacturer gains from the delayed onset of generic competition; the first-filer gains from the absence of generic competition for the first 180 days of marketing.

115. Drug purchasers lose. The brand and first-filer's reciprocal pledges not to compete harm purchasers thrice over. First, the pact delays the first-filer's generic entry into the marketplace and thereby extends the time during which the more expensive brand is the only product on the market. Second, by delaying the first-filer's entry, the pact also delays the time when other, later, generics enter. Finally, the pact prevents the brand from marketing an AG during the 180-day exclusivity period (or beyond), reducing price competition during that period, particularly price competition that would otherwise occur between the first-filer's generic and the brand's AG. In fact, no-AG settlements can in some cases be even more pernicious than straight cash reverse payments as they can cause even more harm to competition, i.e., even greater overcharges to drug purchasers.

116. For the first-filer, the difference between selling the only generic and competing against an AG for 180 days can amount to tens or even hundreds of millions of dollars, depending on the size of the brand's sales. A no-authorized generic pledge thus has the same

economic effect as a payoff made in cash, with even greater anticompetitive consequences as it removes a competitor. As explained by the then-Chairman of the FTC:

> Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, "if you go away for several years, I'll give you $200 million." Now, the brand might say to the generic, "if I launch an AG, you will be penalized $200 million, so why don't you go away for a few years and I won't launch an AG."[51]

Courts agree that no-authorized generic agreements are a form of payment actionable under *Actavis* and are anticompetitive.[52]

117. For a first ANDA filer (like Par) for a brand drug with hundreds of millions in annual sales (like Amitiza), the extra profits from selling a generic without having to compete against another generic, whether AG or otherwise, amount to tens, and in some instances, hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry. No-authorized generic agreements thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

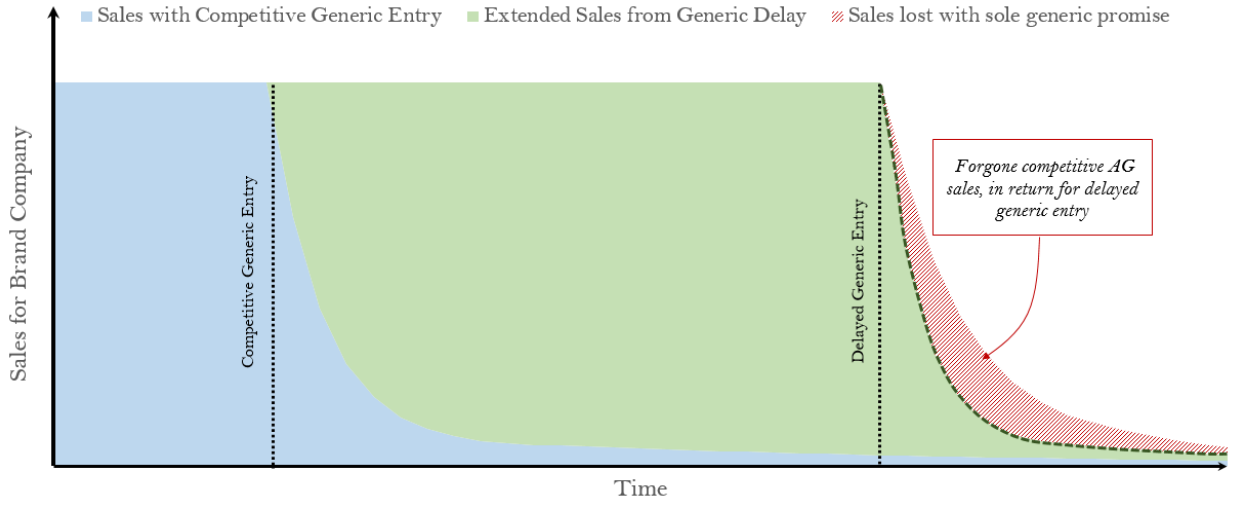
118. Figure 2 depicts what happens when a settlement agreement includes a no-authorized generic promise. The red area shows the brand manufacturer's additional monopoly profits earned during the period of delay. The purple area shows the amount of monopoly profit the brand manufacturer gives up (i.e., shares with the generic).

---

[51] FTC, *Statement of Chairman Jon Leibowitz on the Release of the Commission's Interim Report on Authorized Generics* (June 24, 2009), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authgenstatementleibowitz.

[52] *24 Fe Antitrust Litig.*, 814 F.3d 538, 549 (1st Cir. 2016); *In re Opana ER Antitrust Litig.*, 162 F.Supp.3d 704, 719–20 (N.D. Ill. 2016); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 242 (D. Conn. 2015); *United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069 (N.D. Cal. 2014); *In re Effexor XR Antitrust Litig.*, No. 11-cv-5479, 2014 WL 4988410, at *20 (D.N.J. Oct. 6, 2014); *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 709–10 (E.D. Pa. 2014); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

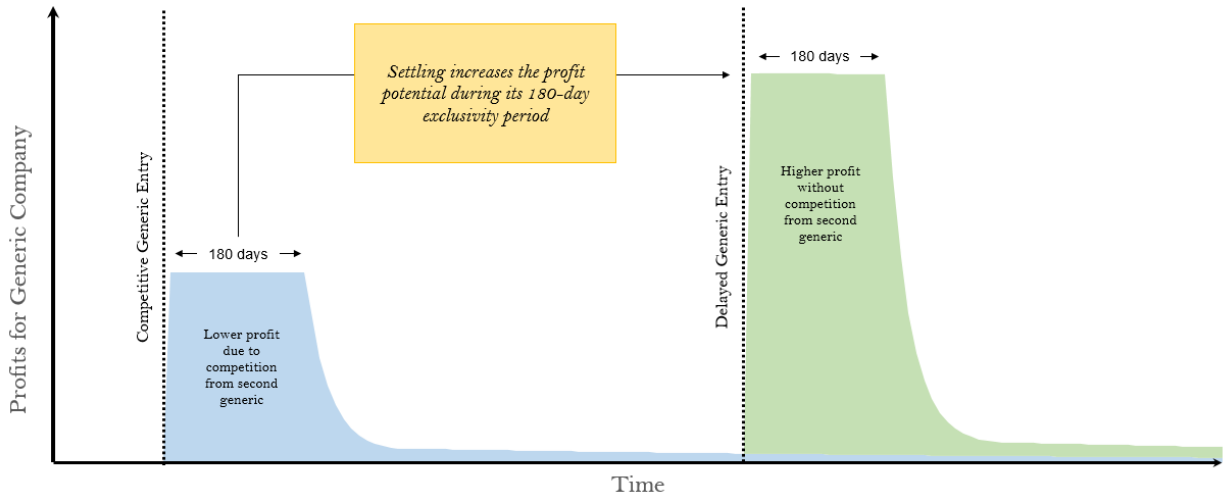
Figure 2: Effect of Delayed Entry on Sales



119. Figure 3 depicts the generic manufacturer's principal considerations in deciding whether to accept a settlement that includes a no-authorized generic agreement. Without a settlement, the generic could enter earlier—either when the 30-month stay expires ("at risk")[53] or when it wins the litigation. The generic manufacturer's profits ("gross margins") would be high during the 180-day exclusivity period and then fall rapidly as additional generics enter. This profit flow is somewhat uncertain because (1) if the generic launches at risk, it could (theoretically) later be found to infringe a valid patent, and (2) it is expected that the brand manufacturer will launch an authorized generic and capture approximately 50% of the generic's sales. With a no-authorized generic promise, the profit flow occurs later but is more certain and is larger—more than twice the size—because the generic manufacturer does not lose half of the market to the brand manufacturer's authorized generic and can charge a higher price.

[53] After a generic receives FDA approval of its ANDA, but before a final court decision as to whether its product infringes the branded product, the generic company may launch "at risk": It can legally come to market with its generic product, but because its product will immediately capture a large share of the market and reduce the brand company's revenue, the generic company is "at risk" of a damages claim by the brand if the brand's patents are found valid and infringed.

Figure 3: Impact of No-AG Promise on Generic's Profits



120. Payoffs by means of no-authorized generic clauses usually exceed the value that the first-filer could have obtained *even if it had won* the patent infringement litigation. By settling the patent case in exchange for a no-authorized generic payoff, the first-filer converts that critical six months (and in this case, potentially up to two years) into a period of *total* generic exclusivity to which it was not otherwise entitled, thus doubling its unit sales and making each of those sales at a higher price.

121. When a brand manufacturer agrees to a no-authorized generic clause in exchange for delaying generic entry, the additional profits gained by causing delay to generic competition to achieve a longer monopoly period significantly outweigh any profit that could have been gained from selling an authorized generic. The bottom line is that the brand manufacturer gains a longer period of monopoly profits by delaying the onset of generic competition, and the generic first-filer maintains higher generic sales and pricing during its 180-day exclusivity period. Thus, no-authorized generic agreements allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

2. Settlements that contain royalty rate structures that decline in the event of an authorized generic launch may constitute an implicit no-authorized generic agreement and/or function as anticompetitive agreements to fix prices.

122. No-authorized generic agreements need not be explicit to achieve their anticompetitive ends. No-authorized generic agreements may be structured to ostensibly or explicitly reserve the brand company's right to sell an authorized generic version of the branded product, but still functionally foreclose the possibility that the brand will launch that product and result in the same impact on competition as an explicit no-authorized generic agreement.

123. The Federal Trade Commission ("FTC") recognizes the existence and impact of such implicit no-authorized generic agreements. For at least a decade, the FTC has observed that even patent settlements that do not contain an "explicit promise not to compete" may still "create[] incentives discouraging the brand from launching an AG that would compete against the first-filer."[54]

124. The FTC has specifically called out agreements with declining royalty structures as those containing a possible reverse payment. In its 2017 study of patent infringement settlements among pharmaceutical companies, the FTC noted that "[a]nother common form of possible compensation [to the settling generic] is an agreement containing a declining royalty structure, in which the generic's obligation to pay royalties is substantially reduced or eliminated if a brand company sells an AG," or more broadly upon the entry of any

[54] FTC, *Authorized Generic Drugs: Short–Term Effects and Long–Term Impact* (Aug. 2011), at 141, *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf. *See also*, FTC, Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2014 (2015), at 2, *available at* https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf ("[A]n agreement containing a declining royalty structure, in which the generic's obligation to pay royalties is reduced or eliminated if a brand launches an authorized generic product, may achieve the same effect as an explicit no-AG commitment.").

other generic product in the market. "[T]his type of provision does not explicitly preclude the brand from launching an AG, but it may achieve the same effect."[55]

125. Coupling a declining royalty structure that financially disincentivizes the brand company from launching an authorized generic version of its branded product with an explicit reservation of the right to do so does not cleanse the agreement of its anticompetitive effects. As courts in this District have observed, an "explicit reservation . . . does not on its own preclude the existence of an implicit no-AG agreement." *Picone v. Shire*, No. 16-cv-12396, 2017 WL 4873506, at *9 (D. Mass. Oct. 20, 2017).

126. Because of the harm to purchasers caused by reverse payment agreements, reverse payment agreements, including no-authorized generic agreements (however disguised), are anticompetitive and unlawful. As the First Circuit explained in considering a no-authorized generic agreement, "antitrust scrutiny attaches not only to pure cash reverse payments, but to other forms of reverse payment that induce the generic to abandon a patent challenge, which unreasonably eliminates competition at the expense of consumers." *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 550 (1st Cir. 2016). Accordingly, if settling brand and generic drug companies agree that the brand "would not launch an AG so that [the generic] would be free from generic competition during its period of market exclusivity, then such an agreement

[55] FTC, *Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2016* (2017), at 2, *available at* https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf.; *see also*, Jamie Towey & Brad Albert, *Then, now, and down the road: Trends in pharmaceutical patent settlements after FTC v. Actavis*, FTC (May 28, 2019), *available at* https://www.ftc.gov/news-events/blogs/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent. *See also* FTC, *Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2017 (2018)*, at 2, *available at* https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma_report_fy2017.pdf ("A declining royalty structure, in which the generic's obligation to pay royalties is reduced or eliminated if a brand launches an authorized generic product. This type of provision may achieve the same effect as an explicit no-AG commitment . . . .").

would violate the Sherman Act." *In re Intuniv Antitrust Litig.*, 496 F. Supp. 3d 639, 671–72 (D. Mass. 2020).

VII. FACTS

A. 1986–1996: Dr Ueno identifies the potential therapeutic benefits of prostones and founds Sucampo to commercialize prostone-based drugs.

127. In or around 1986, Japanese scientist Dr. Ryuji Ueno identified the therapeutic potential of prostones, a type of chemical derived from prostaglandins, lipid-based compounds that naturally occur in the human body. He then set out to patent his discovery. To secure that time-delimited monopoly, he had to make public the details of his invention.

128. On January 28, 1987, Dr. Ueno filed a patent application in Japan that disclosed a novel type of prostaglandin E and its derivatives' potential uses for treating or preventing ulcers.

129. One year later, on January 28, 1988, Dr. Ueno filed a U.S. patent application directed to the same or similar inventions (07/149,445). Dr. Ueno abandoned this initial U.S. application. On September 12, 1989, Dr. Ueno filed a continuation in part application (07/406,830); he abandoned that application as well. On May 13, 1991, Dr. Ueno filed a continuation application (07/700,895); it matured into U.S. patent 5,166,174, directed to specific forms/compounds of prostaglandin E.

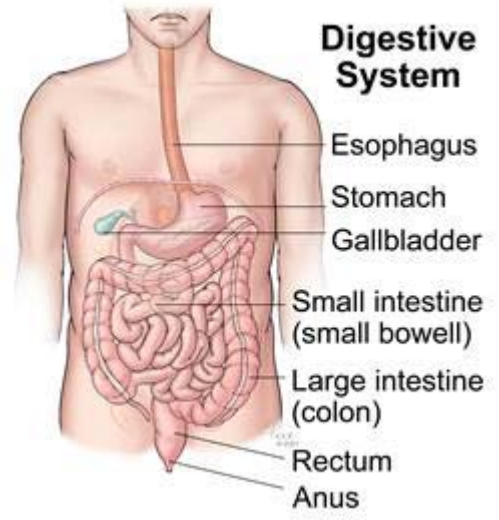
130. On August 6, 1992, Dr. Ueno filed a divisional application to his earlier '895 application. It too claimed specific forms/compounds of prostaglandin E as well as compositions of those compounds and their use as anti-ulcer treatments. It matured into U.S. patent 5,284,858 (discussed further below). (As described further below, the '858 patent claims prostaglandin E(1), from which lubiprostone—the active pharmaceutical compound in Amitiza—is derived).

131. In 1996, with patents in hand, Dr. Ueno and his then-wife and research partner Dr. Sachiko Kuno founded the pharmaceutical company Sucampo in Maryland to develop and commercialize prostone-based drugs for the United States market.[56] Sucampo, along with its partner Takeda, went on to develop and sell the prostone-based constipation drug Amitiza (lubiprostone capsules).

B. How Amitiza works.

132. During the digestive process, the small intestine absorbs water and nutrients from food into the bloodstream, and then passes liquid with waste products into the large intestine. The large intestine also absorbs water in order to process those waste products into solid or semisolid feces for defecation. The following Figure 4 shows the parts of the digestive system:

Figure 4. Diagram of the Digestive System



133. When the normal process of digestion and defecation doesn't work properly, the patient will have difficulty defecating on a regular schedule, which is called constipation.

[56] Takeda, *Takeda and TAP to Promote Sucampo's AMITIZA® in the United States* (Feb. 25, 2007), *available at https://*www.takeda.com/en-us/newsroom/news-releases/2007/takeda-and-tap-to-promote-sucampos-amitiza-in-the-united-states/.

Constipation causes feces to build up in the rectum, which can cause discomfort or pain and various other complications.

134. According to the FDA, *chronic* constipation is through to be a disorder of colonic motility that is present for at least twelve weeks (need not be consecutive) in a year. Chronic *idiopathic* constipation is characterized by infrequent bowel movements that are often difficult to evacuate with no known cause (that is, not due to other diseases or drugs).

135. The active pharmaceutical ingredient in Amitiza is lubiprostone (RU-0211, or SPI-0211), a prostaglandin E1 metabolite analogue. The FDA-approved Amitiza formulation is comprised of a soft gelatin capsule containing lubiprostone and inactive ingredients including a medium-chain fatty acid triglyceride in liquid form.

136. Lubiprostone is a locally acting chloride channel activator that promotes a chloride-rich intestinal fluid secretion without altering sodium and potassium concentration in the serum. Lubiprostone activates a chloride channel in the large intestine that causes the intestine to secrete chloride ions into the lumen (the central opening in the large intestine that waste passes through). Chloride ions are negatively charged, and so their presence draws positively charged sodium ions into the lumen. After that, the presence of both chloride ions and sodium ions draws water into the lumen (since a higher concentration of ions will attract more water, a process known as osmosis). By increasing intestinal fluid secretion, lubiprostone increases motility (movement) in the intestine and also softens the stool, thereby making the patient's defecation easier and more frequent, and alleviating symptoms associated with chronic idiopathic constipation.

137. Presumably, the "lubi-" prefix is intended to suggest "lubrication."

138. Amitiza can also be used to treat irritable bowel syndrome with constipation (IBS-C) in women, a condition in which patients have delayed or infrequent bowel movements,

feces is difficult to pass, and patients experience stomach pain, discomfort, and bloating. The mucosa, the innermost layer of the small intestine, has a barrier function that is intended to allow nutrients and water to pass into the body while excluding pathogens and waste products. IBS-C is often associated with gaps in that barrier. Amitiza helps restore that barrier, in addition to improving the constipation aspect of IBS directly.

139. Amitiza has high efficacy and a low incidence of severe side effects. The most common side effects are nausea and diarrhea.

C. 1999–mid 2004: Sucampo begins the process of seeking FDA approval and conducts Phase III clinical trials.

140. On December 29, 1999, Sucampo submitted the original Investigational New Drug (#59623) for lubiprostone to the FDA. On April 11, 2001, following the conclusion of Phase II studies, Sucampo met with FDA to discuss plans for Phase III development, including the appropriate primary end point.

141. Between September of 2001 and September of 2003, Sucampo conducted two adequate and well-controlled Phase III efficacy studies, SC0131 and SC0232.[57] These two 4-week randomized, placebo-controlled trials in patients with chronic idiopathic constipation showed that lubiprostone twice daily was statistically superior to placebo as measured by spontaneous bowel movement frequency rate during week 1. Sucampo also conducted other studies focused on safety, including a number of open label (meaning, not placebo controlled) studies.

D. October 2004: Lacking resources and experience, Sucampo partners with established pharmaceutical company Takeda to develop, obtain FDA approval for, market, and protect the intellectual property associated with Amitiza.

142. By the fall of 2004, Sucampo had obtained and licensed rights to patents related to lubiprostone (SPI-0211, or RU-0211) and was on its way to submitting an NDA. But it was

[57] SC0131 enrolled 242 subjects (120 in the treatment arm and 122 in the placebo group) and was conducted between September 2001 and August 2002. SC0232 enrolled 237 subjects (119 treatment arm and 118 in the placebo group) and was conducted between October 2002 and September 2003.

a small company and needed help from a more experienced company with deeper pockets, marketing know-how, and manufacturing capabilities.

143. Takeda—a multinational healthcare company with research, development and marketing activities in the U.S.—wanted to obtain potential drug products to develop and commercialize for gastroenterology indications.

144. On October 29, 2004, Takeda Japan and Sucampo entered into a collaboration agreement under which the two companies agreed to cooperate to develop and commercialize lubiprostone. The scope of their cooperation would include working towards regulatory approval for a commercial lubiprostone product, including preparing and submitting an NDA. Sucampo would give Takeda a 16-year license to co-develop, use, sell, promote, offer for sale, import, and distribute the product in the U.S. and Canada. Under the agreement, Sucampo would be primarily responsible for clinical development, while Takeda would be responsible for commercialization, marketing, and sales of the drug.

145. Under the collaboration agreement, Sucampo and Takeda would create a joint steering committee to manage their lubiprostone efforts. The committee was comprised of three executives from Sucampo and three executives from Takeda or its affiliates, and decisions had to be unanimous. It met at least twice a year and kept minutes. The joint steering committee would discuss any changes in market conditions or economic conditions that could affect lubiprostone. If unresolvable disputes arose, the CEO of Sucampo and the CEO of Takeda were required to meet to discuss and resolve the matter.

146. Sucampo and Takeda also established a joint development committee to focus on clinical development of lubiprostone, including getting regulatory approvals. It was comprised of two management representatives appointed by each of Sucampo and Takeda. It met at least quarterly and kept minutes. It, too, operated by unanimous consensus. While this committee

operated jointly, the agreement provided elsewhere that all drug approval applications would be filed in Sucampo's name.

147. Sucampo and Takeda also established a joint commercialization committee and a joint manufacturing committee.

148. The agreement contemplated that Takeda and Sucampo would see additional indications for lubiprostone, and provided that Takeda would pay up to $50 million per each additional indication in accordance with the development plan developed and approved by the joint development committee. Takeda would conduct and fund any required Phase IV studies.

149. Under the agreement, Takeda paid a negotiated price for the Amitiza product, then sold it and paid a royalty back to Sucampo on the sale. For the sixteen-year term of the collaboration agreement, the royalty rate to be paid by Takeda was structured into six tiers based on annual net sales of Amitiza, ranging from 18–26%, resetting each year, putting the vast majority of Amitiza revenue in Takeda's hands throughout the relevant time period.

150. From 2014 through 2020, Takeda retained about 75% of the net sales of Amitiza.

151. The agreement provided Takeda with an exclusive license to the Amitiza patents.

152. Takeda represented and warranted that it would use its best efforts to maximize Amitiza sales revenue in the U.S. and Canada.

153. From the Spring of 2004 on, Takeda was integral to all Amitiza-related business and legal decisions under the collaboration agreement.[58]

154. Takeda and Sucampo also entered into a separate agreement addressing the shared intellectual property. That agreement provided that Takeda and Sucampo shared a goal

[58] All decisions made by the committees were to be "evidenced in a writing signed by one of the members of the JSC from each of the Parties."

of maximizing the patent protection for lubiprostone and its approved indications. Takeda was to be consulted about prosecution of licensed patents and patent strategy for lubiprostone's approved and potential future indications. Takeda was to be consulted before Sucampo filed any patent infringement lawsuits; Takeda had the right to make requests and recommendations concerning defenses in any such lawsuits. Sucampo was obligated to tell Takeda of any infringement or threatened infringement (and vice versa). Takeda had the right to join patent infringement litigation or to commence patent infringement litigation against generic competitors if Sucampo did not do so. In any patent infringement suits brought, Takeda and Sucampo would cooperate with each other.

E. 2005–April 2006: Sucampo applies for, the FDA approves, and Takeda starts selling Amitiza (lubiprostone capsules).

155. On March 31, 2005, Takeda and Sucampo submitted NDA No. 21-908 to the FDA, seeking approval to manufacture, market and sell lubiprostone capsules (later branded Amitiza). It bore only Sucampo's name, as previously agreed.

156. Sucampo and FDA went back and forth about the application, with Sucampo and Takeda discussing at every step. Sucampo made many additional supplemental submissions, over the next ten months.

157. On January 31, 2006, FDA approved Amitiza (lubiprostone capsules, 24 mcg) for the treatment of chronic idiopathic constipation in adults.

158. Sucampo (with Takeda's blessing) initially submitted patent information asking the FDA to list the '858, '032, '016, and '174, patents in the Orange Book, with expirations then between February 8, 2011 (pre-extension) and August 30, 2022.

159. In April 2006, Takeda began selling Amitiza in the U.S. Takeda was responsible for most of the marketing, sales, and other commercialization efforts for Amitiza from that time

forward.[59] From then on, Takeda and Sucampo jointly (and unanimously) determined how to maximize Amitiza sales/revenue, pursue approval of additional indications. As discussed above, Takeda retained the vast majority of revenues from sales of Amitiza.

F. In total, Sucampo and Takeda submit seventeen patents for listing in the Orange Book; Only the '858 patent presented a legitimate barrier for ANDA applicants as the later-issued patents ostensibly covering Amitiza and its uses were easy to design around or carve out.

160. Over time, seventeen patents ostensibly claiming aspects of Amitiza and its uses were filed for and/or obtained through assignment and listed in the FDA's Orange Book.

[Chart Begins Next Page]

[59] Sucampo retained the right to co-promote and sell Amitiza.

Patent	Description	Issued (Expired)	Par's Position	Asserted against Par?
'858	Lubiprostone compound patent	February 8, 1994 (July 14, 2014)	Paragraph III	N/A
'016	Method Of Use: U-1392 (001) U-717 (001) U-874 (002)	July 2, 2002 (September 5, 2020)	Paragraph IV	Yes
'613	Method Of Use: U-1203 (001) U-1393 (001) U-1202 (002)	December 6, 2011 (September 5, 2020)	Paragraph IV	Yes
'653	Method Of Use / Composition: U-1214 (001) U-1394 (001)	January 17, 2012 (November 14, 2022)	Paragraph IV	Yes
'542	Formulation	March 5, 2013 (November 14, 2022)	Paragraph IV	Yes
'312	Method Of Use: U-1085 (002)	September 14, 2010 (September 17, 2024)	Paragraph IV	Yes
'639	Gel Cap Formulation	December 25, 2012 (January 23, 2027)	Paragraph IV	Yes
'393	Gel Cap Formulation	September 27, 2011 (October 25, 2027)	Paragraph IV	Yes
'174	Formulation	June 24, 2003 (October 16, 2020)	CNS[60]	No
'067	Formulation	August 26, 2008 (October 16, 2020)	CNS	No
'649	Formulation	January 17, 2012 (October 16, 2020)	CNS	No
'890	Formulation and Gel Cap Formulation	February 14, 2012 (September 5, 2020)	CNS	No
'934	Formulation	January 3, 2012 (May 18, 2021)	CNS	No
'148	Method Of Use: U-1404 (001) U-739 (002)	June 2, 2006 (August 30, 2022)	CNS	No

[60] "CNS" stands for "covenant not to sue." As described in Section VII.L., a later-filing generic manufacturer alleged that Par received a covenant not to sue on these patents from Takeda and Sucampo.

Patent	Description	Issued (Expired)	Par's Position	Asserted against Par?
'283	Method Of Use: U-1391 (001)	January 3, 2006 (December 4, 2022)	Unclear[61]	No
'481	Method Of Use: U-1520 (001) U-1519 (002)	June 10, 2014 (September 1, 2025)	Issued after ANDA filed	No
'187	Gel Cap Formulation	July 15, 2014 (January 23, 2027)	Issued after ANDA filed	No

161. U.S. Patent No. 5,284,858 (the "'858 patent") covers prostaglandin E(1), from which lubiprostone—the active pharmaceutical compound in Amitiza—is derived. The '858 patent was the Amitiza drug substance, or compound, patent and the strongest patent in the Amitiza arsenal. It expired on July 14, 2014 (with a regulatory extension).[62]

162. The remaining sixteen patents listed in the Orange Book had expiration dates ranging from 2020 and 2027 and fall into three categories.

163. Seven patents claim methods of treating various diseases by administering certain drug products. These patents are U.S. Patent Nos.:

7,064,148 (the "'148 patent");
8,748,481 (the "'481 patent");
6,982,283 (the "'283 patent");
7,795,312 (the "'312 patent");
6,414,016 (the "'016 patent");
8,071,613 (the "'613 patent"); and
8,097,653 (the "'653 patent").

[61] The '283 patent contained narrow claims directed only to methods of treating drug-induced constipation (such as opioid-induced constipation) that could have been addressed with a § viii carve out. The '481 patent issued after Par's ANDA was filed, and appeared in the Orange Book starting in June 2014. The '187 patent issued after Par's ANDA was filed, and appeared in the Orange Book starting in July 2014. None of these three were ever asserted against Par.

[62] Section 156 of the patent laws allows for extension of patent term for the period of time the drug was caught up in FDA review, allowing patentees to reclaim some of their term from when they weren't yet allowed to market their inventions. The '858 patent originally expired February 8, 2011. It received 1,252 days of patent term extension, which extended its expiry date to July 14, 2014.

Amitiza was only approved to treat three indications. The methods of use claimed were far broader. As described above, an ANDA applicant need not seek approval for all of the indications/methods of use for which the brand drug has been approved. It may submit a section viii statement and omit from the proposed labeling a method of use protected by a listed patent.[63]

164. Four patents claim drug product compositions. These patents are U.S. Patent Nos.:

8,088,934 (the "'934 patent");
6,583,174 (the "'174 patent");
7,417,067 (the "'067 patent"); and
8,097,649 (the "'649 patent").

165. Five patents claim simple pharmaceutical formulations of prostaglandins. These patents are U.S. Patent Nos.:

8,114,890 (the "'890 patent");
8,779,187 (the "'187 patent");
8,389,542 (the "'542 patent");
8,026,393 (the "'393 patent"); and
8,338,639 (the "'639 patent").

166. Again, generics can modify their formula slightly to avoid infringing composition and formulation patents while still satisfying the FDA's conditions of approval. And later-issued composition and formulation patents must stand on their own as non-obvious in light of, and as not anticipated by, the disclosures in earlier patents, applications, or other publications.

167. The weak nature of the patents and their claims, as detailed below, meant that none of these additional patents stood as legitimate impediments to generic competition,

[63] Section 505(j)(2)(A)(viii).

though the listing of them in the Orange Book meant that every potential generic competitor would have to address them.

168. Neither Takeda nor Sucampo ever asserted the '174, '067, '649, '890, '934, or '148 patents against a would-be generic competitor. They gave a covenant not to sue on these patents to at least one generic company. These patents did not prevent a generic company from coming to market.

169. Takeda and Sucampo only asserted seven of the patents ostensibly covering Amitiza against Par.

G. June 2007–April 2008: Sucampo and Takeda sought, and the FDA granted, approval for a second indication: treatment of Irritable Bowel Syndrome with constipation in adult women.

170. On June 29, 2007, Sucampo submitted a supplemental new drug application ("sNDA") for 8 mcg Amitiza capsules for treatment of Irritable Bowel Syndrome with constipation in adult women.

171. On April 29, 2008, the FDA approved the application. Per the terms of the commercialization agreement, Sucampo and Takeda worked jointly to obtain and then maximize revenue from this new indication.

H. August 2010: FDA suggests ways that generic companies can establish bioequivalence for lubiprostone capsules.

172. In February 2010, Anchen submitted ANDA 201442 to the FDA seeking approval to manufacture, market, and sell a generic version of Amitiza in 8 and 24 mcg strengths once the '858 drug substance patent expired on July 14, 2014.

173. On June 11, 2010, the FDA issued final guidance describing a new process for informing the public how it recommends designing product-specific bioequivalence studies to support ANDAs: FDA would announce the availability of a new or updated product-specific guidance by publishing a notice in the federal register. It would post the draft or final

bioequivalence recommendations on its website. The federal register notice would identify a comment period, open to the public and industry, and contain instructions on how comments shall be submitted. The FDA stated that "[t]he public is encouraged to submit comments" through the designated channel and that it "will consider received comment in developing final BE [bioequivalence] recommendations." FDA explained that it "adopted this process as a means to develop and disseminate product-specific BE recommendations and provide an opportunity for the public to consider and comment on those recommendations."

174. Six months after Anchen submitted its ANDA, in August 2010, FDA took three actions with respect to lubiprostone generics: it issued a draft bioequivalence guidance, it published information about how to conduct dissolution testing, and it refused to accept Anchen's initial ANDA until such time as it had re-done its bioequivalence studies.

1. FDA issues a draft guidance for generic lubiprostone capsules.

175. In August 2010, the FDA issued a draft guidance containing recommendations to applicants seeking approval of ANDAs for generic versions of Amitiza. Such guidance is consistent with long-standing practice of the FDA as a science-driven agency.

176. Neither draft nor final guidance are required for the FDA to approve an ANDA. Guidance documents represent the FDA's current thinking on a particular topic. They do not bind the FDA or the public; sponsors can and do use alternative approaches to establish, e.g., bioequivalence if that approach satisfies the requirements of the applicable statutes and regulations. This is written at the top of every draft and final guidance documents, accompanied by the suggestion that "[i]f you want to discuss an alternative approach, contact the Office of Generic Drugs."

177. Posting a draft guidance, and seeking comment on it, shows that the FDA is well underway in evaluating the circumstances under which it would approve an ANDA for a

particular product. The August 2010 issuance of the draft guidance for lubiprostone capsules was a clear signal to the drug industry that the FDA had studied the applicable science and actively considered, and would continue to consider, the circumstances under which it would accept for filing, and approve, ANDAs for generic Amitiza. FDA had done that work in connection with the bioequivalence information included in Anchen's ANDA.

178. The 2010 Draft Guidance recommended two bioequivalence studies for ANDAs for orally administered lubiprostone capsules: (1) a comparative pharmacokinetic ("PK") study of the 24 mcg dose in healthy males and females and (2) a comparative clinical endpoint study of the 24 mcg dose conducted in adults with chronic idiopathic constipation ("CIC").[64] These recommendations applied to all generic formulations, regardless of how similar they were to the Amitiza formulation (e.g., regardless of whether they had qualitatively (Q1) and quantitatively (Q2) the same inactive ingredients as Amitiza).

179. The guidance also recommended conducting dissolution testing on 12 dosage units, and referred to further product-specific dissolution testing information to be provided in the FDA's online Dissolution Methods Database.

180. The Federal Register notice explained that "FDA believes that making this information available on the Internet will . . . provide a meaningful opportunity for the public to consider and comment on product-specific BE study recommendations." It also provided instructions for submitting comments "at any time," either electronically via http://www.regulations.gov or in writing by mailing them to a specified address for the Division of Dockets Management.

[64] FDA also indicated that in vivo bioequivalence testing of the 8 mcg dose could be waived based on (1) acceptable bioequivalence studies on the 24 mcg strength, (2) proportional similarity of the formulation across all strengths, and (3) acceptable in vitro dissolution testing on all strengths.

2. FDA provides information for lubiprostone dissolution testing.

181. Also in August 2010, the FDA updated its Dissolution Methods Database to include details about suggested dissolution methods for lubiprostone (as referenced in the draft guidance). Sometimes, a sponsor and FDA wind up going back-and-forth about whether the sponsor's methods of actually conducting the recommended dissolution testing are adequate. Here, the FDA identified how it wanted dissolution testing to be done up front. This again reflects that FDA had considered appropriate bioequivalence methods in detail.

3. FDA asks Par's predecessor, Anchen, to amend its ANDA to include additional clinical study data.

182. In August 2010, Anchen received a refuse to receive ("RTR") notification from the FDA indicating that Anchen's generic Amitiza ANDA would need to be amended to include additional clinical study data. That is, Anchen would need to conduct the kind of studies described in the draft guidance (or use an FDA-accepted alternative approach that satisfied the applicable statutes and regulations).

I. 2011–June 2012: Par completes the clinical studies recommended by the 2010 Draft Guidance.

183. Faced with FDA's suggestion that it conduct additional studies, Anchen (and later Par) moved full steam ahead; they conducted the studies, and encountered no unexpected challenges that prevented them from either completing the studies or establishing that their proposed formulation was bioequivalent to Amitiza.

184. In January 2011, Anchen hired Novum Pharmaceutical Research to conduct the studies suggested by the FDA, agreeing to pay it a total of $6.4 million.

185. In May 2011, they began recruiting for a phase III, three-arm (Amitiza, generic, placebo), double-blind randomized clinical study using the 24 mcg dose (as described in the draft guidance). Ultimately, 808 subjects enrolled. The primary end point was establishing the

clinical equivalence of Amitiza and Anchen's lubiprostone formulation treatments and the superiority of each active treatment over the placebo in the change from baseline in mean number of SBM's during the 7-day randomization period of the study (as recommended in the draft guidance).

186. In November 2011, Par acquired Anchen, including all rights to its lubiprostone ANDA. Anchen had already paid Catalent about $3.4 million. Par did not stop the ongoing bioequivalence studies. It assumed responsibility for the remaining $3 million owed (which included a royalty on future sales of lubiprostone).

187. The clinical study concluded in June 2012. Shortly thereafter, Par submitted the results of the studies recommended by the guidance to FDA, and the FDA accepted Par's lubiprostone ANDA for filing.

188. As the first generic to submit a substantially complete ANDA for lubiprostone, Par was potentially eligible for 180-days of ANDA exclusivity for generic Amitiza when it received approval—meaning, no other ANDA generic could be sold during that time (though an AG could be).

J. July 2012: Takeda and Sucampo jointly announce filing a supplemental NDA seeking approval for a third indication: treatment of opioid-induced constipation in patients with chronic, non-cancer pain.

189. On or around July 26, 2012, Sucampo and Takeda announced the filing of a sNDA with FDA seeking approval for a new indication for Amitiza for the treatment of opioid-induced constipation in patients with chronic, non-cancer pain.

190. Opioid-induced constipation is one of the most common side effects of opioid-based medicines, which are used in the management of chronic pain. OIC affects the majority of patients treated chronically with opioids. Some patients discontinue opioid therapy and thereby endure pain rather than suffer from the constipation the opioids cause.

191. "This submission is an important milestone for both companies," said Charlie Baum, Vice President, U.S. Medical Affairs, Takeda.

K. December 26, 2012: Par sends a paragraph IV notice challenging Amitiza patents.

192. On December 26, 2012, Par sent a paragraph IV notice letter to Sucampo, representing it had filed an ANDA seeking approval to manufacture, market, and sell a generic version of Amitiza following expiration of the '858 drug substance patent in 2014.[65] On information and belief, Par's notice letter claimed that all of the other twelve patents then listed in the Orange Book as covering Amitiza were invalid, unenforceable, or would not be infringed by Par's generic product. Sucampo represented that it received the letter on January 2, 2013.

193. On January 24, 2013, Par sent a second paragraph IV notice letter, certifying that the newly issued '639 patent was invalid, unenforceable, and/or not infringed by Par's generic Amitiza product.

L. February 2013: Takeda and Sucampo sue Par, triggering the 30-month stay of approval of the first potential generic competitor (to expire on July 2, 2015).

194. On February 7, 2013, Takeda and Sucampo sued Par in the United States District Court for the District of Delaware for alleged infringing claims of six method of use and gel cap formulation patents: the '016, '613, '312, '393, '653, and '639 patents.[66] Because it filed within 45 days of receiving Par's initial paragraph IV notice, the 30-month stay did not end, and so FDA could not approve Par's ANDA, until on or around July 2, 2015.

195. In April 2013, the FDA approved Amitiza for treatment of OIC in adult patients with chronic, non-cancer pain, which was later qualified to add the language "including patients

[65] *Sucampo AG v. Anchen Pharms., Inc.*, No. 13-202 (D. Del. Feb. 7, 2013), ECF No. 1.

[66] *Sucampo AG. v. Anchen Pharms., Inc.*, No. 13-202 (D. Del. Feb. 7, 2013).

with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation."

196. On May 7, 2013, Par sent a third Paragraph IV notice letter certifying that the newly issued '542 patent was invalid, unenforceable, and/or not infringed by Par's generic Amitiza product.

197. On July 3, 2013, Takeda and Sucampo amended their complaint to allege infringement of claims of the '542 patent.

198. As detailed in Section VII.R., *infra*, none of the asserted patents would have acted to bar generic entry by Par. Because the '639 and '542 patents were obtained after Par filed its ANDA, they did not trigger a 30-month stay nor otherwise present a barrier for Par to obtain FDA approval or enter the market.[67] The '187 and '481 patents were likewise obtained after Par filed its ANDA, and therefore did not trigger a 30-month stay nor otherwise present a barrier for Par to obtain FDA approval or enter the market. Takeda and Sucampo never asserted any of the '542, '187, or '481 patents in litigation against Par.

199. At no point in the litigation did Sucampo and Takeda accuse Par of infringing the '174, '067, '649, '890, '934, or '148 patents. These patents did not present a barrier for Par to obtain FDA approval or enter the market. These unasserted patents were included in the Covenant Not to Sue obtained by a later-filing generic manufacturer, discussed below. That later-filing generic manufacturer alleged that Par received the same covenant not to sue on these patents.

[67] The Hatch-Waxman Act allows only one 30-month stay for each ANDA, even where the NDA holder has listed multiple patents for the same NDA. *See Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed; Final Rule*, 68 Fed. Reg. 36,676 (June 18, 2003).

200. The '283 patent did not present a barrier for Par to obtain FDA approval or enter the market either. That patent contained narrow claims directed only to methods of treating opioid-induced constipation that could have been addressed with a section viii carve out. Takeda and Sucampo never asserted the '283 patent in litigation against Par.

201. The litigation proceeded through discovery, with competing claim construction briefs filed on January 17, 2014.

M. January 2014: Sucampo, in collaboration with Takeda, files a baseless citizen petition.

202. On January 17, 2014, the same day that it submitted its claim construction brief, Sucampo (with Takeda's knowledge, input, and approval as to this regulatory strategy) submitted a citizen petition to the FDA asking the FDA not to approve generic versions of Amitiza unless they conducted additional onerous and unnecessary bioequivalence tests. The petition requested that the FDA "revise its existing proposed criteria for how to demonstrate bioequivalence for lubiprostone capsules as set forth in this petition," and "apply such revised criteria to any abbreviated new drug application ("ANDA") that relies upon the new drug application ("NDA") for AMITIZA® (lubiprostone) capsules (NDA 21-908) as the reference listed drug." To those ends, the petition stated that the FDA's existing guidance was not sufficient to ensure that generic Amitiza formulations have "the same safety profile" as Amitiza in all three approved indications.

203. A reasonable pharmaceutical manufacturer in Takeda and Sucampo's position would not realistically expect the FDA to grant its specific requests. The petition would not move the FDA to grant the relief requested for at least the following reasons:

204. First, the petition is premised on the notion that it is incumbent on ANDA applicants to conduct clinical studies to prove that their generic drugs are safe and effective. But that inverts the statutory structure imposed by Congress and the FDA's regulations and

practices implementing that structure. As described above, ANDA applicants need not independently prove safety and efficacy so long as they establish bioequivalence. And the statute requires the FDA to approve an ANDA "unless" the information in an ANDA is insufficient to show bioequivalence.[68] The FDA has repeatedly explained this to drug companies, including in earlier citizen petition responses.[69]

205. Second, the petition did not include data or information showing that a generic approved under the recommendations outlined in the 2010 draft guidance would work differently in the body than the brand, or have clinically meaningful consequences. It merely speculated:

- "A generic lubiprostone product *could* demonstrate pharmacokinetic bioequivalence of a single-dose of 48 mcg, while having up to a 25% higher plasma concentration than AMITIZA. This higher effective dose *could* result in more adverse events."[70]

- "a lubiprostone product that is more potent than AMITIZA *could* achieve efficacy endpoints but lead to diarrhea, and eventually, dehydration."

The FDA had repeatedly shot down similar, speculative and unsupported fear-mongering, including in past citizen petition denials. It had also mounted a public education campaign to dispel myths about generics drugs that had been perpetuated by, e.g., similar scientifically unsupported handwringing.

206. Third, in light of the statutory scheme and FDA's regulations and practices implementing that scheme, Sucampo's requests violated the FDA's stated goal of avoiding unnecessary experimentation on humans.

---

[68] 21 U.S.C. § 355(j)(4)(F). There are other disqualifying criteria listed in 355(j)(4); we address only those relevant here.

[69] *See, e.g.*, FDA's Denial of GlaxoSmithKline's Citizen Petitions Concerning Flonase, at 21 (Feb. 22, 2006). Citizen petitions and responses are publicly available, including through regulations.gov. Brand companies follow citizen petition responses quite closely, so much so that a defense law firm maintains a publicly available index (including linked copies of all petitions and responses) to make it even easier to do so.

[70] Emphasis added, footnote omitted.

207. Takeda and Sucampo could have submitted their comments on the draft guidance in the manner FDA requested and at the time that FDA requested feedback. They didn't. Instead, they chose a process known to delay generic approvals and strategically timed the filing of the petition to potentially push the approval of Par's ANDA out past the expiration of the 30-month stay.

208. At the time, Takeda and Sucampo knew that Par had filed an ANDA for lubiprostone capsules and knew or had reason to know that Par had approached bioequivalence in the manner recommended by the FDA in the 2010 draft guidance. Information about Par's clinical trial, including its design and end points, was available through clinicaltrials.gov. Asking the FDA to impose additional requirements on ANDA applicants was asking the FDA to require that Par do even more work (and expensive, time-consuming, and scientifically unnecessary work at that) before approving Par's ANDA.

N. September 2014: Takeda and Sucampo enter into an anticompetitive agreement with Par, sharing monopoly profits with Par in exchange for Par's agreement to stay off the market until 2021.

209. In September 2014, Takeda and its partner Sucampo, on the one hand, and Par, on the other, entered into the Takeda/Sucampo-Par 2014 agreement, under which (1) Par agreed to delay launching a generic version of Takeda's Amitiza until January 1, 2021, (2) when Par eventually did launch, there would only be one generic in the market (whether Par's ANDA product alone or an authorized generic distributed by Par only), with the sides agreeing to split the generic revenue 50/50, and (3) Takeda/Sucampo agree to prolong the one-generic-only artifice by keeping other generics out of the market for as long as they possibly could (again, "Takeda/Sucampo-Par 2014 agreement").

210. The Takeda/Sucampo-Par 2014 agreement is only in part reflected in a September 30, 2014 written settlement document that also resolved some patent litigation (the

"written settlement document.") The written settlement document reflects some of the anticompetitive terms, fails to disclose others, and in part is written to obscure the true anticompetitive effect of the overall Takeda/Sucampo-Par 2014 agreement. For years, Takeda, Sucampo and Par concealed the anticompetitive aspects of their agreement by, among other things,[71] disclosing a false and illusory reservation by Takeda/Sucampo of the ability to launch their own authorized generic product, while keeping hidden the royalty structure that shows it economically non-sensical for them to actually do so, and by telling the district court overseeing the patent infringement litigation that their settlement agreement was "procompetitive."

211. At heart, the Takeda/Sucampo-Par 2014 agreement is an agreement to have one, *and only one*, generic on the market for at least six months and up to two years and to split between them the monopoly profits resulting from having only a single generic on the market. The agreement is agnostic as to whether the single generic is an ANDA product or an authorized generic, and the overcharges suffered by plaintiffs and the class likewise are the same regardless of whether the generic product is an ANDA product or an AG. What matters is that there is only one generic on the market. As detailed below, the split of monopoly profits created by the anticompetitive agreement results in a large reverse payment to Par which induced Par to delay its entry and which caused plaintiffs and the class to pay overcharges. The written settlement document not only does not contain all of these terms but in fact works to obscure them to give the illusion of a procompetitive settlement.

212. Par agreed to delay selling a generic version of Amitiza until January 1, 2021. Once it entered, Par would pay a declining royalty on its gross profits from the sales of generic

[71] The defendants' efforts to conceal the anticompetitive agreement are described further in Sections VII.O. & XII.

Amitiza based on the number of other generic entrants; specifically, Par would pay (1) 50% as the only generic on the market, (2) 15% with one other generic on the market (whether an authorized generic ("AG") or a third-party ANDA generic), and (3) no royalty with two or more additional generics.

213. The Takeda/Sucampo-Par 2014 agreement gave Par the option to market AG Amitiza as of January 1, 2021 instead of manufacturing and selling Par's own generic Amitiza under its ANDA. The agreement's terms—and specifically the 50% profit split/royalty—would apply whether Par sold AG Amitiza or its own ANDA generic Amitiza.

214. While Takeda and its partner Sucampo technically reserved the ability to launch their own authorized generic product in the written settlement document, the Takeda/Sucampo-Par 2014 agreement ensured that there would only be a single generic (either ANDA or AG) because economics created by the structure of the agreement ensured that both the brand companies and Par would be better off if Takeda never launched an AG to compete with Par's launch. Whether Par marketed its own ANDA generic Amitiza or an AG Amitiza provided by Takeda, all of the defendants would be better off with no additional generic competition.

215. As described above (Section V.A.), AB-rated generics are commodity products; they compete on price. The more AB-rated generics on the market, the lower their prices. The greatest downward pressure on generic prices comes when a second generic enters. Before then, the sole generic typically prices at a small discount to the brand. With additional entrants, the discount increases, reducing prices for purchasers and profits for manufacturers.

216. The Takeda/Sucampo-Par 2014 agreement made it far more profitable for both Takeda and Par for Par to be the only generic on the market—whether as the sole AG or through its own ANDA. Though Par's royalty rate would drop from 50% to 15% if another

generic or AG were on the market, the higher royalty rate was still more profitable for Par because, in the absence of other generic or AG competition, Par would realize much higher unit sales at much higher prices. Similarly, the agreement made it far more profitable for Takeda not to launch an AG, since it would earn more by not launching an AG and instead receiving a larger royalty on Par's sales at a higher price as the sole generic on the market, than it would by launching an AG that would compete with Par's ANDA product, drive prices down, and result in much lower overall revenues, including a lower royalty.

217. Takeda was incentivized to keep all generics other than Par out for as long as possible, and that included being incentivized not to launch its own authorized generic. If another generic launched, Takeda's royalty from Par would drop from 50% to 15%, and the generic price would also fall due to competition.

218. Under normal, lawful circumstances, brand companies license third parties to market and sell authorized generics to compete with ANDA generics, as a means to recoup some of the sales that the ANDA generic(s) will take. Indeed, on at least four occasions, Takeda has done just this for its own drugs:

Takeda Drug Name	**Date of authorized generic entry**	**Third party marketing and selling the authorized generic**
Duetact (pioglitazone and glimepride)	Aug. 4, 2015	Prasco
Kazano (alogliptin and metformin)	Apr. 2016	Perrigo
Nesina (alogliptin)	Apr. 2016	Perrigo
Oseni (alogliptin and pioglitazone)	Apr. 2016	Perrigo

219. Now-public documents produced in another pharmaceutical antitrust case state that the industry standard for AG licenses outside of pay-for-delay settlements has the generic company launching the AG paying 90% of its profits to the brand company. The

Takeda/Sucampo-Par 2014 agreement required only a 50% royalty. This far-below market rate royalty was an effective large payment to Par, designed to get Par to agree to a long delay in generic entry for Takeda's benefit, and to agree not to challenge the weak patents on Amitiza.

1. The value of the Takeda/Sucampo-Par 2014 agreement to Takeda and Par during the first 180-days of the "one generic only" period.

220. Each year, purchasers spend hundreds of millions of dollars on Amitiza. According to IQVIA, Amitiza U.S. sales were about $427 million for the 12 months ending on Sept. 30, 2020.

221. As part of the Takeda/Sucampo-Par 2014 agreement, Takeda and Par agreed to a period of "one generic only" on the market that extended for at least 180-days. A reasonable estimate of the value of that agreement to Takeda and Par for the first 180 days follows.

222. Absent the anticompetitive Takeda/Sucampo-Par 2014 agreement, and using industry standards, if Par launched its ANDA product, and the brand launched an AG, the two generics would be priced at approximately 60% of the brand, they together would take 90% of all lubiprostone unit sales, and Par would make half of the generic sales. Par's revenues during the first 180 days (when other ANDA generics are foreclosed from the market by FDA regulation) would be ($427 million) * (0.5 year) * (0.6 percentage of the brand price) * (0.9 generic penetration) * (0.5 of the generic market) = $57.6 million. And Takeda would make the same amount if it launched an AG, $57.6 million.

223. Under the Takeda/Sucampo-Par 2014 agreement, both Par and Takeda will make far more revenue due to their agreement to monopolize the generic market and divide the monopoly profits. If Par marketed the AG (as it elected to do) and Takeda did not launch another AG (which, in fact, Takeda didn't), using industry standards, Par's AG would be priced at about 90% of the brand, and would take 90% of all lubiprostone unit sales, and 100% of all generic sales. Par's revenues during the first 180 days would be ($427 million) * (0.5 year) *

(0.9 percentage of the brand price) * (0.9 generic penetration) * (1 sole entrant in the generic market) = $173 million. Par would pay a 50% royalty to the brand and retain the other 50% = $86.5 million.

224. The payment to Par is the difference between its revenues under the Takeda/Sucampo-Par 2014 agreement ($86.5 million), and what it would have received absent any anticompetitive terms ($57.6 million), which is $28.9 million. This difference of $28.9 million is an unlawful reverse payment from Takeda to Par *just during the first 180 days*. And Takeda's reverse payments to Par appear to continue for four times that long: up to two full years.

225. The same result would occur under the Takeda/Sucampo-Par 2014 agreement if Par elected to come to market with its ANDA generic Amitiza rather than by commercially marketing Takeda's AG.

226. Either way, the Takeda/Sucampo-Par 2014 agreement was structured to ensure that it would be economically irrational for the brand to launch another generic to compete with Par. Doing so would both decrease the prices that the generics could charge (thus reducing the universe of potential profits) and decrease the amount of the royalty to be paid by Par to the brand. With an AG on the market, instead of making $86.5 million each during those first 180 days, Par's revenues would be ($427 million) * (0.5 year) * (0.6 percentage of the brand price) * (0.9 generic penetration) * (0.5 of the generic market) * (.85 retained profit after royalty) = $49 million.

227. Takeda's revenues for an AG during that time would be ($427 million) * (0.5 year) * (0.6 percentage of the brand price) * (0.9 generic penetration) * (0.5 of the generic market) * (1.15 full AG profit plus 15% royalty from Par) = $66.3 million, far less than the

$86.5 million that Takeda receives under the terms of the Takeda/Sucampo-Par 2014 agreement.

228. Therefore, under the Takeda/Sucampo-Par 2014 agreement, it would make no economic sense for Takeda to launch an AG, because it earns more by not launching an AG ($86.5 million) than by launching an AG ($66.3 million). Of course, Takeda did not in fact launch an AG (other than the one that Par marketed), unlike Takeda's prior course of conduct with numerous other drugs.

229. If Takeda launched an AG, putting two generics on the market, Par would pay a smaller royalty on smaller profits, and the foregone royalty payments would cost Takeda more than it would gain in revenues from AG sales. No economically rational actor would take that option.

230. Takeda, Sucampo, and Par all knew that while Par had the choice to either market the AG or launch its own ANDA product, Takeda would not launch its own AG in either case and therefore, no matter what form Par chose, there would only be one generic on the market regardless of what purported rights any party retained. That is, the Takeda/Sucampo-Par 2014 agreement was at least a de facto no-authorized generic agreement, since it provided for a single generic to have the entire generic market in return for delayed generic entry and a share of the revenues.

231. The value of this de facto no-authorized generic agreement to Par just during the first 180 days of its generic entry is at least $28.9 million, the difference between Par's likely revenue under the Takeda/Sucampo-Par 2014 agreement and Par's likely revenue absent the agreement.

232. This effective payment to Par of at least $28.9 million induced Par to accept a delay of its generic entry until January 2021 and drop its challenge to the vulnerable Amitiza patents.

233. This effective payment of $28.9 million far exceeds any reasonable estimate of litigation expenses that Takeda and Sucampo would have saved by settling the litigation with Par.

2. The value of the Takeda/Sucampo-Par 2014 agreement to Takeda and Par of the up to two-year "one generic only" period.

234. As part of the anticompetitive agreement, Takeda and Par agreed to a "one generic only" period that extended for up to two years. A reasonable estimate of the size of that payment follows.

235. Assuming roughly constant Amitiza sales and 90% generic penetration at 90% of the brand price, Par's estimated revenues over that two-year period would be ($427 million) * (2 years) * (0.9 generic penetration) * (0.9 percentage of the brand price) = $692 million. After paying a 50% royalty, Par will retain about $346 million.

236. Absent any anticompetitive agreements, Par and Takeda would each have earned $57.6 million in the first 180 days of generic entry, as explained above. After the first 180 days, there would have been at least a Takeda AG and a Par ANDA generic, and possibly other ANDA generics all sharing the 90% generic share of the market at a lower price. If the Takeda AG and the Par ANDA generic were the only generics on the market, they would each earn ($427 million) * (1.5 years) * (0.9 generic penetration) * (0.6 percentage of the brand price) * (0.5 each generic's share of the market) = $173 million over that period. Par and Takeda's total generic revenues for that two-year period would have been only ($57.6 million) + ($173 million) = $231 million each. With additional generic entrants after the 180-day period, the

generic price would have been even lower and the generic market split more ways, and Takeda and Par's revenues would have been much lower.

237. The value of two years of generic exclusivity to Par is the difference between the revenue that it will receive during the two years after paying a 50% royalty ($346 million) and what it would have received absent any anticompetitive agreements (at most $231 million), which is at least $115 million.

238. Takeda's increased revenue from the two years of Par's generic exclusivity is the difference between the amount that Takeda will receive over those two years in royalty payments from Par ($346 million), and what Takeda would have received in revenue absent any anticompetitive agreements (at most $231 million), which is at least $115 million.

239. The value of these unlawful reverse payments far exceed what Par would have earned had it prevailed in the patent litigation, and these payments induced Par to accept a delay of its generic entry until January 2021 and drop its challenge to the vulnerable Amitiza patents.

240. Under applicable law, Par would forfeit its 180-day exclusive period if it did not receive tentative approval within 30 months of filing its ANDA, which would have been at some point between December 2014 through June 26, 2015.[72] Par did not receive tentative approval for its ANDA, and therefore potentially forfeited its 180-day exclusive period. Not only did the settlement allow Par to receive an exclusive period that it had potentially forfeited, but that exclusivity period lasted for two years rather than just 180 days. As mentioned above, the value of this generic exclusivity to Par is at least $115 million.

[72] At which point, Par has already settled with the option to launch an AG, so was not motivated to pursue its own ANDA, and would have reported its license to the FDA. That it did not obtain tentative approval does not mean that it would not have obtained tentative or final approval in the absence of the anticompetitive Takeda/Sucampo-Par 2014 agreement.

3. The value of the settlement to Sucampo is substantial.

241. Sucampo publicly announced the settlement with Par in a press release issued and 8-K filed around the close of business on Oct. 9, 2014. On October 10, 2014, Sucampo's stock price increased by an adjusted return of +11.5%, one of the two largest stock price increases Sucampo experienced over the preceding four months, and reflecting that Sucampo's investors understood that the Takeda/Sucampo-Par 2014 agreement would be highly profitable for Sucampo.[73] And what was profitable for Sucampo would be far more so for Takeda, which received the vast majority of the revenues from Amitiza.

242. Through the Takeda/Sucampo-Par 2014 agreement, Takeda postponed generic competition for several years, and Takeda sold brand Amitiza at supracompetitive prices during those years without any danger of losing most of the market to cheaper generics.

243. The delay achieved by Takeda/Sucampo-Par 2014 agreement meant billions more in sales of Amitiza to Takeda.

O. Fall 2014: Par, Sucampo, and Takeda conceal the true terms of the Takeda/Sucampo-Par 2014 agreement from the district court and the public, and Takeda takes even more control of the Amitiza franchise.

244. On October 9, 2014, Sucampo, in conjunction with Takeda and Par, issued a press release announcing the settlement of Takeda's and Sucampo's infringement litigation against Par, stating that "under the terms of the settlement," Par was granted:

> *a non-exclusive license* to market Par's generic version of lubiprostone 8 mcg soft gelatin capsule and 24 mcg soft gelatin capsule (licensed products) in the U.S. for the indications approved for AMITIZA beginning January 1, 2021, or earlier under certain circumstances. Beginning on January 1, 2021, Par *will split* with Sucampo the gross profits of the licensed products sold during the term of the agreement, which continues until each

[73] Thomas McGuire et al., *Resolving Reverse-Payment Settlements with the Smoking Gun of Stock Price Movements* 101 IOWA L. REV. 1581 (2016), Harvard Pub. L. Working Paper No. 16-18, *available at* SSRN: https://ssrn.com/abstract=2593944 ("An otherwise unexplained bump in the patent holder's stock price shows that the settlement created new future profits by extending the period without generic competition beyond what the stock market expected.")

> of the Sucampo patents has expired. In the event Par elects to launch an authorized generic, Sucampo will supply Par under the terms of a manufacturing and supply agreement at a negotiated price. Additional details of the agreement remain confidential.

245. The press release misrepresented and obfuscated the true terms of the Takeda/Sucampo-Par 2014 agreement. The agreement did not, in fact, provide Par with a "non-exclusive" license. Takeda had agreed not to enter the market with its own, competing authorized generic product indefinitely while the two companies split the supra-competitive profits from the "one generic only" period. The press release was also misleading because the term "split" when referencing how gross profits would be divided among the parties misrepresents the royalty structure. A "split" implies, but does not necessarily mean, a 50/50 division. But the royalty structure ultimately revealed shows a diminishing royalty would be paid to Takeda in the event that other generic products entered the market (including a Takeda authorized generic product).

246. On November 7, 2014, Sucampo filed a redacted version of the September 30, 2014 written settlement document with the SEC in its Q3 2014 10-Q filing.[74] Here too Takeda and Sucampo misrepresented and concealed the true terms of the Takeda/Sucampo-Par 2014 agreement:

247. Takeda/Sucampo redacted the royalty rates that Takeda would earn upon Par's launch, on the one hand, and when additional generic products came to market, on the other. That is, it concealed the economic disincentive for Takeda to actually launch an authorized generic.

248. And yet, Sucampo disclosed, and did not redact, a provision stating that "[n]othing in this Agreement shall restrict the ability of Sucampo [and Takeda], from

[74] Again, the September 30, 2014 written settlement document reflects only part of the Takeda/Sucampo-Par 2014 agreement.

launching, Commercially Marketing and/or selling an Authorized Generic or from licensing a Third Party to launch, Commercially Market and/or sell an Authorized Generic, or from launching, Commercially Marketing, and selling any product for indications or dosages not set forth in Par's ANDA."

249. Takeda's ostensible reservation of the ability to launch a competing authorized generic was delusive. Takeda's actual agreement was that it would not, in fact, launch a competing authorized generic. And, in fact, Takeda did not launch an authorized generic in January 2021 and has not to this day.

250. Adding to their deception, on November 21, 2014, Takeda, Sucampo, and Par filed on the docket in the Par patent infringement litigation a proposed consent judgment, for which they sought approval of the district court. The proposed consent judgment, entered on December 2, 2014, stated that the settlement "*will afford Plaintiffs and Par the procompetitive opportunity* to more productively use money and other resources that would have been spent in the continued prosecution and defense of this Patent Litigation, *to the benefit of the parties and consumers alike* . . . ." (emphasis added). These statements were false and further concealed the true nature of the Takeda/Sucampo-Par 2014 agreement from the district court and from the public. Takeda agreed to withhold from consumers a competing product, which would have reduced the prices paid for Amitiza and Par's generic Amitiza. That is the opposite of a procompetitive agreement.

251. In October 2014, just after the Takeda/Sucampo-Par 2014 agreement with Par was done, Takeda and Sucampo amended their 2004 collaboration agreement to provide for an extension of its term beyond December 31, 2020, after which time they would share evenly in the annual net sales revenue on branded Amitiza sales.

252. Sucampo then ceased all direct sales of Amitiza in the United States by the end of the 2014 calendar year, leaving Takeda solely responsible for the marketing and sale of the drug in the U.S. market throughout the entire class period. Up to that point, Sucampo had made a small number of direct sales of Amitiza in the U.S.

P. July 2015: At the time that Par's 30-month stay would have expired, the FDA denied the citizen petition and revised the draft guidance to make it easier for generics to show bioequivalence.

253. On July 17, 2015, days after Par's 30-month stay would have ended, the FDA denied Sucampo's citizen petition. In doing so, the FDA stated that the petition's request that generics provide clinical data demonstrating an equivalent safety profile was based on the "incorrect" premise that different lubiprostone products may have different safety profiles. The FDA stated there was no "reason[] to question" the "decades of scientific data on the variability of product characteristics" "or the statistical standards used to ensure meaningful bioequivalence results." The FDA explained that if generic Amitiza products that are qualitatively (Q1) and quantitatively (Q2) the same as to the reference listed drug, the FDA said the notion that the generic product could have a "different safety profile from Amitiza is speculative and *not supported by any scientific basis.*"

254. At the same time, the FDA revised the draft guidance to make it easier for generics to show bioequivalence. It did not add any of the tests proposed by the petition; rather, it *removes* the need for Q1 and Q2 generics to conduct the clinical studies recommended by the earlier guidance.

Q. January 2021: Par comes to market with its authorized generic Amitiza, and was and still is the only generic Amitiza product available.[75]

255. On January 4, 2021, Endo International plc, Par's corporate parent, announced that Par had "begun shipping the first authorized generic versions of [...] Amitiza (lubiprostone) 8mcg and 24 mcg capsules," confirming Par's election to proceed as the AG, rather than under its own ANDA.

256. Takeda and Sucampo have not launched their own AG and instead are sharing in the monopoly profits generated by the Par-marketed AG being the only generic on the market.

R. In the absence of the Takeda/Sucampo-Par 2014 agreement, two generics would have been available, at a much lower price point, as early as July 17, 2015; more generics would have followed.

257. In the absence of the Takeda/Sucampo-Par 2014 agreement, two generics would have been available, and at a much lower price point, as early as July 17, 2015 and in any event well before January 4, 2021 on a date to be estimated by the jury.

258. The FDA would have approved Par's ANDA on July 17, 2015, when the FDA denied the citizen petition and lowered the bar – but not the scientific standard—for conducting bioequivalence studies for lubiprostone (as explained in Section VII.P.).

259. A competitively acting generic company in Par's position would have launched thereafter, on a date to be estimated by a jury. In similar circumstances, a generic almost always launches at risk, after a district court decision on the merits at the latest (but often before).[76] Par itself had launched at risk at least four times before, including at least twice launching before a district court decision on the merits.

[75] According to Medi-Span data, as of the date of the filing of this complaint, there remains just one generic Amitiza product on the market (Par's authorized generic).

[76] *See, e.g.*, Keith M. Drake et al., *No Free Launch: At-Risk Entry by Generic Drug Firms*, NBER Working Paper 29131 (Aug. 2021), *available at* http://www.nber.org/papers/w29131.

260. A competitively acting company in Takeda's position would have launched an authorized generic to compete with Par. In similar circumstances, a brand almost always launches an authorized generic when the first generic comes to market.[77] Takeda itself had launched at risk at least six times before.

261. In the absence of the anticompetitive agreement, additional generics would have been available, at an even lower price point, thereafter.

S. None of the patents asserted by Takeda and Sucampo against Par posed an impediment to generic entry.

262. Par detailed in legally-mandated notification letters why its ANDA products did not infringe any of the Orange Book patents. As did other generics. While these notification letters are not publicly available, their existence is not in doubt, and their contents will provide compelling evidence—along with the January 1, 2021 entry date for Par agreed to by Takeda and Sucampo, providing for entry years before the expiry of their ostensible patent protection (but still achieving significant generic delay)—that none of the asserted patents would have prevented generic entry upon expiry of the '858 drug substance patent on July 14, 2014.

263. As to the seven patents asserted against Par, Par answered and counter-claimed, asserting that each of the patents asserted were invalid, unenforceable, and/or not infringed and, accordingly, that none are impediments to the generic Amitiza ANDA products.

264. In the stark light of patent infringement litigation, if brought to a decision on the merits, the four later-issued drug product composition patents (the '934, '174, '067, and '649 patents) would not have survived, given (e.g.) that their claims are not patentably distinct from the claims of the '858 patent (or indeed from each other).[78] That they were never asserted

[77] *See, e.g.*, FTC 2011 AG Study.

[78] The claim construction order issued by Chief Judge Sleet in the District of Delaware litigation against Par put to rest any argument that the bicyclic compounds claimed in these four patents differ from the monocyclic compounds claimed in the '858 patent. *See* Order Construing the Terms of U.S. Patent Nos. 7,795,312; 8,026,393;

against Par (or any of the generics against whom the Amitiza patents were litigated) underscores Takeda's and Sucampo's view that none of these patents posed any true impediment to any generic Amitiza ANDA filer.

265. Neither the '148 nor the '890 patents were asserted against any generic Amitiza ANDA filer. The brand also did not assert the '481, '283, or '187 patents against Par, underscoring that the patents posed no impediment to generic Amitiza market entry.

266. Of the seven (of sixteen) Orange Book-listed patents asserted against Par, none claimed the drug substance lubiprostone by itself. Four claimed methods of treating various diseases by administering certain drug products and three claimed simple formulations of prostaglandins.

267. Method of use patents, like all patents, must claim novel and non-obvious improvements over the prior art to be upheld in court.[79] All four method of use patents asserted against Par (and at least one other generic Amitiza ANDA filer) claimed methods of using the prostaglandin compounds to treat constipation and/or irritable bowel syndrome. The use of prostaglandin compounds to treat constipation and irritable bowel syndrome was well known in the art at least as early as 1987, many years prior to the earliest filed of the method of treatment patents asserted against Par. Accordingly, all the methods of use patents would have been found invalid, unenforceable, and/or not infringed by the manufacture, use or sale of the generics' ANDA products, and therefore would not have impeded Par's market entry for generic Amitiza absent the 30-month stay.

8,338,639; 8,097,653, and 8,389,542, C.A. No. 13-cv-202-GMS (D. Del. May 5, 2014) [ECF No. 96] (ordering "that the claimed 13,14-dihydro-15-keto-16,16-difluoro prostaglandin E1 compounds can exist in either monocyclic or bicyclic form, as well as mixtures of both forms.").

[79] 35 U.S.C. §§ 102, 103.

268. The three formulation patents would likewise have been held invalid, unenforceable, and/or not infringed by the manufacture, use or sale of the generics' ANDA products. Each of them claims formulations of prostaglandin compounds, using known excipients to formulate a pharmaceutical dosage form (at least two of which are gel cap formulations). For example, the gel cap has been known in the art for nearly 200 years (that is not a typo); none of the claims would have met the standard of non-obviousness to prevent Par's market entry for generic Amitiza absent the 30-month stay.

269. In short, the patents that Takeda and Sucampo actually sued Par on were vulnerable, easily designed around formulation and method of use patents. The asserted patents posed no real barrier to entry, outside of the 30-month stay that sprang from instituting the litigation. Takeda and Sucampo did not sue Par on ten patents, and lopped years off the life of their patents but still achieved significant generic delay, recognizing that the Amitiza patents would not be legitimate barriers to entry.

VIII. CLASS ALLEGATIONS

270. The plaintiffs bring this action as a class action under Rules 23(a), 23(b)(2), and (b)(3) of the Federal Rule of Civil Procedure on behalf of themselves and as representatives of a class defined as follows:

> All persons and entities in the United States and its territories that directly purchased brand Amitiza, authorized generic Amitiza, and/or generic Amitiza in any form from Takeda; Par; or any other generic Amitiza manufacturer, or their subsidiaries or affiliates, from July 17, 2015 until the effects of defendants' conduct cease.

271. Excluded from the class are Takeda, Par, and any of their officers, directors, management, employees, parents, subsidiaries, and affiliates.

272. Also excluded from the class are the government of the United States and all agencies thereof.

273. The class seeks damages for at least the four years preceding the date this complaint was filed, but from as early as July 17, 2015 forward as a result of the defendants' fraudulent concealment and continuing violations, as detailed below.

274. Members of the class are so numerous and geographically dispersed that joinder of all members is impracticable. The class is numerous and widely dispersed throughout the United States. Given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The class is readily identifiable from information and records in the defendants' possession.

275. The plaintiffs' claims are typical of the claims of the members of the class. The plaintiffs and all members of the direct purchaser class were damaged by the same wrongful conduct of the defendants—i.e., as a result of the defendants' conduct, they paid artificially inflated prices for Amitiza, AG Amitiza, and/or will continue paying artificially high prices for Amitiza, AG Amitiza, and/or generic Amitiza.

276. The plaintiffs will fairly and adequately protect and represent the interests of the class. The interests of the plaintiffs are coincident with, and not antagonistic to, those of the other members of the class.

277. Counsel who represent the plaintiffs are experienced in the prosecution of antitrust class action litigation and have particular experience with antitrust class action litigations involving pharmaceutical products and antitrust claims.

278. Questions of law and fact common to the members of the class predominate over questions that may affect only individual class members, because the defendants have acted on grounds generally applicable to the entire class, thereby making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in the defendants' wrongful conduct.

279. Questions of law and fact common to the class include:

a. Whether the defendants unlawfully maintained monopoly power as a result of the Takeda/Sucampo-Par 2014 agreement;

b. Whether there exist any legitimate procompetitive reasons for some or all of the defendants' conduct;

c. To the extent such justifications exist, whether there were less restrictive means of achieving them;

d. Whether direct proof of the defendants' monopoly power is available and, if so, whether it is sufficient to prove the defendants' monopoly power without the need to define the relevant market;

e. Whether the defendants' scheme, in whole or in part, has substantially affected interstate commerce;

f. Whether the Takeda/Sucampo-Par 2014 agreement, in whole or in part, caused antitrust injury through overcharges to the business or property of plaintiffs and the members of the class;

g. Whether the defendants conspired to delay generic competition for Amitiza;

h. Whether the Takeda/Sucampo-Par 2014 agreement included a reverse payment;

i. Whether, pursuant to the Takeda/Sucampo-Par 2014 agreement, Takeda and Sucampo's effective promise not to compete against Par's generic product constituted a payment;

j. Whether the Takeda/Sucampo-Par 2014 agreement was necessary to yield some cognizable, non-pretextual procompetitive benefit;

k. Whether Takeda's compensation to Par was large and unexplained;

l. Whether the reverse payment harmed competition;

m. Whether, before January 1, 2021, Takeda possessed the ability to control prices and/or exclude competition for Amitiza;

n. Whether the defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Amitiza or in causing some amount of delay in the market entry of multiple competing AB-rated generic Amitiza products;

o. Determination of a reasonable estimate of the amount of delay the defendants' unlawful monopolistic conduct caused; and

p. The quantum of overcharges paid by the class in the aggregate.

280. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

281. The plaintiffs know of no special difficulty to be encountered in litigating this action that would preclude its maintenance as a class action.

IX. MARKET POWER AND RELEVANT MARKET

282. The pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Amitiza, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy, while the patient (and in most cases his or her insurer) has the obligation to pay for the product.

283. Brand manufacturers, including Takeda, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products.[80] These sales representatives do not advise doctors of the cost of the branded products. Studies show that doctors typically are not aware of the relative costs of

[80] As a result of automatic substitution laws that require or encourage pharmacies to prescribe generic products when available, explained *supra*, ¶72, generic manufacturers need not, and do not, operate in the same way.

brand pharmaceuticals and, even when they are aware of the relative costs, they are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

284. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the cross-price elasticity of demand—the extent to which rising prices of a product cause unit sales to decline because of substitution to other products. This reduced cross-price elasticity, in turn, gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including Amitiza.

285. Before January 4, 2021, Takeda had monopoly power in the market for Amitiza because it had the power to exclude competition and/or raise or maintain the price of lubiprostone at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable. From January 4, 2021 on, Takeda and Par combined had and will continue to have substantial market power in the market for Amitiza and its generic equivalent, because they had and will have the power to exclude competition and/or raise or maintain the price of lubiprostone at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable.

286. Before January 4, 2021, a small but significant, non-transitory increase to the price of brand Amitiza would not have caused a significant loss of sales. From January 4, 2021 on, a small but significant, non-transitory increase in the price of generic Amitiza would not have caused and will not cause a significant loss of sales.

287. Brand Amitiza does not exhibit significant, positive cross-elasticity of demand with respect to price with any other drug or treatment other than AB-rated generic versions of Amitiza.

288. Takeda (and, later, Takeda and Par) needed to control only brand Amitiza and its AB-rated generic equivalents, and no other products, in order to maintain the price of lubiprostone profitably at supra-competitive prices. Only the market entry of competing, AB-rated generic versions of Amitiza would render the defendants unable to profitably maintain their prices for Amitiza and generic Amitiza without losing substantial sales.

289. For several years, Takeda sold brand Amitiza at prices well in excess of marginal costs and in excess of the competitive price, and therefore, Takeda had high profit margins.

290. From January 2021 through the present, Par sold AG Amitiza at prices well in excess of marginal cost and in excess of the competitive price, and therefore, Par had high profit margins.

291. From the present on, Par will sell AG Amitiza at prices well in excess of marginal cost and in excess of the competitive price, and therefore, Par will continue to have high profit margins.

292. Takeda and Sucampo had, and exercised, the power to exclude generic competition to brand Amitiza.

293. Takeda Sucampo, and Par had and will continue to have, and exercised and will continue to exercise, the power to exclude generic competition to the Par-marketed AG.

294. At all material times, high barriers to entry, including regulatory protections and high costs of entry and expansion, protected brand Amitiza from the forces of price competition.

295. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show the defendants' ability to control the price of brand Amitiza and generic Amitiza, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, inter alia, the following facts: (1) generic Amitiza would have entered the market at a much earlier date, at a substantial discount to brand Amitiza, but for the defendants' anticompetitive conduct; (2) Takeda's gross margin on Amitiza (including the costs of marketing and its share of Sucampo's ongoing research/development costs) at all relevant times was very high; and (3) Takeda never lowered the price of Amitiza to the competitive level in response to the pricing of other brand or generic drugs.

296. To the extent proof of monopoly power by defining a relevant product market is required, the plaintiffs allege that the relevant antitrust market is the market for Amitiza and its AB-rated generic equivalents.

297. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

298. Takeda's market share in the relevant market was 100% until January 4, 2021, after which Takeda and Par, collectively, had and will have 100% market share in the relevant market.

X. MARKET EFFECTS AND DAMAGES TO THE CLASS

299. The defendants willfully and unlawfully maintained their market power by entering into the Takeda/Sucampo-Par 2014 agreement. The agreement had the anticompetitive effect of maintaining supra-competitive prices for the relevant product.

300. The defendants' acts, including in performing under the agreement, in combination and individually, were undertaken to serve the defendants' anticompetitive goals.

301. The defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Amitiza, and later the Par-marketed AG Amitiza, from competition. These actions allowed the defendants to maintain a monopoly and exclude competition in the market for brand Amitiza and its generic equivalent, to the detriment of the plaintiffs and all other members of the direct purchaser class.

302. The defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Takeda to sell brand Amitiza without generic competition, and then for Par to sell AG Amitiza without generic competition. Were it not for the defendants' illegal conduct, one or more generic versions of Amitiza would have entered the market sooner and Par's generic would have faced competition during its 180-day exclusivity period from an authorized generic.

303. The defendants' illegal acts and conspiracy to delay generic competition for Amitiza caused the plaintiffs and all members of the class to pay more than they would have paid for Amitiza absent this illegal conduct.

304. Typically, generic versions of brand drugs are priced significantly below the brand counterpart. As a result, upon generic entry, direct purchasers substitute generic versions of the drug for some or all of their brand purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and the brand drug continues to lose even more market share to the generics. This price competition enables all direct purchasers of the drug to purchase generic versions at a substantially lower price, and/or purchase the brand drug at a reduced price. Consequently, brand drug manufacturers have a keen financial interest in delaying the onset of generic competition.

305. Generic companies holding first-to-file exclusivity likewise have a keen financial interest in delaying their entry into the market in exchange for (1) maintaining generic exclusivity, and (2) a share of the monopoly profits that their delay makes possible. Additionally, purchasers experience substantial cost inflation from these delays, since they have to pay full price for the brand version of the drug over that period instead of a much cheaper price for generics.

306. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, direct purchasers, such as the plaintiffs and members of the class, would have paid less for Amitiza by (1) paying lower prices for their remaining brand purchases of Amitiza; (2) substituting purchases of less-expensive generic Amitiza for their purchases of more-expensive brand Amitiza; and/or (3) purchasing generic Amitiza at lower prices sooner.

307. Thus, the defendants' unlawful conduct deprived the plaintiffs and members of the class of the benefits from the competition that the antitrust laws are designed to ensure.

308. As a consequence, the plaintiffs and other members of the class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

XI. ANTITRUST IMPACT AND EFFECT ON INTERSTATE COMMERCE

309. During the relevant time period, the defendants manufactured, sold, and shipped Amitiza and generic Amitiza across state lines in an uninterrupted flow of interstate commerce.

310. During the relevant time period, the plaintiffs and members of the class purchased substantial amounts of Amitiza and/or AG Amitiza directly from the defendants. As a result of the defendants' illegal conduct, the plaintiffs and the members of the class were compelled to pay, and did pay, artificially inflated prices for Amitiza and AG Amitiza.

311. From the present until the effects of defendants' conduct cease, plaintiffs Meijer and KPH as well as members of the class will make future purchases in substantial amounts of Amitiza, AG Amitiza, and/or generic Amitiza directly from the defendants, and/or other generic Amitiza manufacturers. As a result of the defendants' illegal conduct, the plaintiffs and the members of the class will be compelled to pay, and will pay, artificially inflated prices for Amitiza, AG Amitiza, and/or generic Amitiza.

312. During the relevant time period, the defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All the defendants engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce.

313. The defendants' conduct was within the flow of, and was intended to have and did have a substantial effect on, interstate commerce in the United States, including in this District.

314. During the class period, each defendant, or one or more of each defendant's affiliates, used the instrumentalities of interstate commerce to join or effectuate the scheme. The scheme in which the defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

XII. CONTINUING VIOLATIONS AND FRAUDULENT CONCEALMENT

315. A cause of action accrued for the plaintiffs each time the defendants sold a brand or generic Amitiza product to the plaintiffs at a supra-competitive price made possible by their anticompetitive conduct. And each sale by the defendants of a product at a supra-competitive price constituted another overt act in furtherance of their anticompetitive scheme.

316. Due to the defendants' fraudulent concealment of their unlawful conduct, however, the plaintiffs and members of the class are entitled to recover damages reaching back even beyond four years of the filing of this complaint. That Takeda and Sucampo paid Par in the form of a functional no-authorized generic promise (or "one generic only" agreement) was not fully revealed until after Par launched its authorized generic Amitiza product on January 4, 2021, and neither Takeda nor any other licensed third party launched another authorized generic version of Amitiza. At that point, it became clear that there would not be competition for generic Amitiza and that Takeda/Sucampo-Par 2014 agreement was the reason for that.

317. The plaintiffs and members of the class had only limited, inferential knowledge of the defendants' unlawful scheme and could not have discovered the full and ultimate extent of the scheme and conspiracy through the exercise of reasonable diligence more than four years before the filing of this complaint.

318. The defendants' scheme was concealed by the defendants' deceptive tactics and techniques of secrecy to avoid detection of, and to conceal, their contract, combination, conspiracy and scheme.

319. The defendants and co-conspirators wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from the plaintiffs and members of the class. From the time that the Takeda/Sucampo-Par 2014 agreement was entered, the defendants repeatedly referenced the agreement and Par's agreement to delay its entry until January 2021, but consistently, consciously, and actively omitted that Par's agreement to delay was provided in exchange for Takeda's promise not to compete with Par by launching its own authorized generic Amitiza product during at least the first six months of Par's presence on the market, but potentially for up to two years. The concealment scheme played out as follows:

320. On October 9, 2014, Sucampo, in conjunction with Takeda and Par, issued a press release announcing the Par settlement, telling the public that under the agreement, Par was granted:

> *a non-exclusive license* to market Par's generic version of lubiprostone 8 mcg soft gelatin capsule and 24 mcg soft gelatin capsule (licensed products) in the U.S. for the indications approved for AMITIZA beginning January 1, 2021, or earlier under certain circumstances. Beginning on January 1, 2021, Par *will split* with Sucampo the gross profits of the licensed products sold during the term of the agreement, which continues until each of the Sucampo patents has expired. In the event Par elects to launch an authorized generic, Sucampo will supply Par under the terms of a manufacturing and supply agreement at a negotiated price. Additional details of the agreement remain confidential.

321. The press release was misleading because the agreement between Takeda and Par did not, in fact, provide Par with a "non-exclusive" license. Under their overarching agreement, Takeda agreed not to enter the market with its own, competing authorized generic product indefinitely while the two companies split the supra-competitive profits from having one generic only on the market. The press release was also misleading because the term "split" when referencing how gross profits would be divided among the parties misrepresents the royalty structure. A "split" implies, but does not necessarily mean, a 50/50 division. But the royalty structure ultimately revealed shows a diminishing royalty would be paid to Takeda in the event that other generic products entered the market (including a Takeda authorized generic product).

322. On November 7, 2014, Sucampo filed the written settlement document with the SEC in its Q3 2014 10-Q filing, redacting, among other terms, the royalty rates that Par would pay upon its launch and in the event that additional generic products came to market during the term of the agreement.

323. These redactions were intended to, and did, obscure the true nature of the overall anticompetitive agreement, particularly because the parties intentionally left unredacted Takeda's (illusory) reservation of its ability to launch a competing authorized generic product. The declining royalty structure that would only later be revealed demonstrates Takeda's disincentive to launch an authorized generic product to compete with Par's generic product in direct contradiction of its supposed reservation.

324. On November 21, 2014, Takeda, Sucampo, and Par jointly filed on the docket in the Par patent infringement litigation a proposed consent judgment, for which they sought approval of the district court. The proposed consent judgment, entered on December 2, 2014, stated that the settlement "*will afford Plaintiffs and Par the procompetitive opportunity* to more productively use money and other resources that would have been spent in the continued prosecution and defense of this Patent Litigation, *to the benefit of the parties and consumers alike* . . . ." (emphasis added).

325. The consent judgment filed with the district court was false and misleading. The agreement between Takeda and Par was not procompetitive. It was the exact opposite and there was no benefit to consumers: Takeda agreed to withhold from consumers a competing product, which would have reduced the prices paid for Amitiza and Par's generic Amitiza.

326. Only after Par actually launched its authorized generic product in January 2021, and Takeda did not launch a competing authorized generic product, did it become clear that the Takeda/Sucampo-Par 2014 agreement was in fact an agreement by Takeda not to launch a competing authorized generic Amitiza product in exchange for Par's delayed entry. Takeda's promise not to launch a competing authorized generic was for at least 180 days, but potentially for up to two years. While the written settlement document technically gave Takeda the right to launch an authorized generic, it was clear to all parties that Takeda would not actually do

this. That Takeda did not actually launch an authorized generic when Par launched reveals that earlier public statements to the contrary were misleading, and lends plausibility to the plaintiffs' allegations.

327. From October 2014 forward, the defendants made numerous public statements and filings concerning the Takeda/Sucampo-Par 2014 agreement and Par's forthcoming generic Amitiza product, including partial disclosures of significant terms of the written settlement document portion of that agreement. Yet those statements never disclosed the agreement for what it actually is: an agreement by Takeda and Par to have a period of "one generic only" and to split the profits so long as they can keep other generics out of the market.

328. Because the scheme and conspiracy were affirmatively concealed by the defendants, the plaintiffs and members of the class had insufficient knowledge of the scheme and conspiracy more than four years before the filing of this complaint; and lacked the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed and if the facts or information had been available to them and they attempted an investigation, that investigation would not have revealed the existence of the defendants' unlawful conspiracy.

329. The plaintiffs and members of the class also lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred. Reasonable diligence on the part of the plaintiffs and members of the class would not have uncovered those facts more than four years before the filing of this complaint.

330. As a result of the defendants' fraudulent concealment, all applicable statutes of limitations affecting the plaintiffs' and class members' claims have been tolled.

XIII. CLAIMS FOR RELIEF

COUNT ONE – VIOLATION OF 15 U.S.C. §1 (AGAINST TAKEDA AND PAR)

331. The plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

332. Takeda and Par violated 15 U.S.C. § 1 by entering into an and/or furthering an unreasonable restraint of trade by execution of and adherence to the Takeda/Sucampo-Par 2014 agreement, of which the September 30, 2014 written settlement document was only one component. The agreement (1) included an unlawful reverse payment consisting of Takeda's agreement not to launch it's a second generic Amitiza for at least the first six months, but potentially up to two years, of Par's marketing a generic Amitiza product, and (2) constituted an agreement to allocate the market for branded and generic Amitiza for at least six months, but potentially up to two years.

333. The plaintiffs and other members of the class have been injured in their business or property by the violation of 15 U.S.C. § 1. Their injury consists of having paid higher prices for lubiprostone than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed to prevent, and it flows from that which makes the defendants' conduct unlawful. The plaintiffs, as direct purchasers or assignees of direct purchasers from Takeda and Par (and potentially other generic manufacturers in the future) are the proper entities to bring a case concerning this conduct.

334. From the launch of brand Amitiza in 2006 through January 3, 2021, Takeda possessed monopoly power in the relevant market—i.e., the market for sales of lubiprostone in the United States. But for the defendants' wrongful conduct, as alleged herein, Takeda should

have lost its monopoly power in the relevant market as early as July 17, 2015 and in any event well before January 4, 2021.

335. On or about Sept. 30, 2014, Takeda and Par entered into the Takeda/Sucampo-Par 2014 agreement, of which the September 30, 2014 settlement document was only a part, a reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under which Takeda paid Par substantial consideration in exchange for Par's agreement to delay bringing its generic version of Amitiza to the market. The purpose and effect of doing so was to (1) delay generic entry of Amitiza in order to lengthen the period in which Takeda's brand Amitiza could monopolize the market and make supra-competitive profits; (2) ensure that when Par eventually did launch, there would only be one generic in the market (whether Par's ANDA product alone or an authorized generic distributed by Par only), thereby allowing the defendants to reap and share monopoly profits during that period; and (3) raise and maintain the prices that the plaintiffs and other members of the class would pay for Amitiza at supra-competitive levels from January 4, 2021 through the present and continuing.

336. The Takeda/Sucampo-Par 2014 agreement's reverse payment component covered a sufficiently substantial percentage of the relevant market to harm competition.

337. The Takeda/Sucampo-Par 2014 agreement also constitutes a market allocation agreement. Takeda and Par agreed to allocate the market by agreeing that there would be only one generic on the market for at least six months and up to two years, a foreseeable consequence of which was that the price of the first generic to market was significantly higher than it would have been in the presence of competition from a second (or more) generic. Takeda and Par agreed to split, and actually split, the monopoly profits resulting from the supra-competitive prices. In exchange for Par agreeing to preserve Takeda's monopoly through January 4, 2021, Takeda agreed not to launch a competing generic during when Par came to

market and for as long as they could keep other generics off the market and to share the supracompetitive profits.

338. Takeda and Par are liable for their anticompetitive agreement under a "rule of reason" standard under the antitrust laws.

339. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

340. As a direct and proximate result of Takeda and Par's anticompetitive conduct, including entering into and performing under the Takeda/Sucampo-Par 2014 agreement, the plaintiffs and other members of the class were harmed.

DEMAND FOR JUDGMENT

WHEREFORE, the plaintiffs, on behalf of themselves and the proposed class, respectfully demand that this Court:

A. Determine that this action may be maintained as a class action pursuant to Rules 23(a), 23(b)(2), and 23(b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the class, and declare the plaintiffs as representatives of the class;

B. Enter joint and several judgments against the defendants and in favor of the plaintiffs and the class;

C. Award the class injunctive relief;

D. Award the class damages (i.e., three times overcharges) in an amount to be determined at trial;

E. Award the plaintiffs and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

F. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the plaintiffs, on behalf of themselves and the proposed class, demand a trial by jury on all issues so triable.

Dated: September 17, 2021

Respectfully submitted,

HAGENS BERMAN SOBOL SHAPIRO LLP

/s/Kristen A. Johnson
Thomas M. Sobol (BBO #471770)
Kristen A. Johnson (BBO #667261)
Bradley J. Vettraino (BBO #691834)
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Tel: (617) 482-3700
Fax: (617) 482-3003
tom@hbsslaw.com
kristenj@hbsslaw.com
bradleyv@hbsslaw.com

Attorneys for FWK Holdings LLC, Meijer, Inc., Meijer Distribution Inc., KPH Healthcare Services, Inc., a/k/a. Kinney Drugs, Inc. and the Proposed Class

Michael L. Roberts
Stephanie E. Smith
ROBERTS LAW FIRM US, PC
20 Rahling Cir.
Little Rock, AR 72223
Tel: (501) 821-5575
mikeroberts@robertslawfirm.us
stephaniesmith@robertslawfirm.us

Attorneys for KPH Healthcare Services, Inc., a/k/a. Kinney Drugs, Inc. and the Proposed Class

Joseph M. Vanek (BBO # 551083)
David P. Germaine (*pro hac vice*)
Eamon P. Kelly (*pro hac vice*)
John P. Bjork (*pro hac vice*)
SPERLING & SLATER, P.C.
55 W. Monroe St., Suite 3200
Chicago, IL 60603
Tel: (312) 641-3200
jvanek@sperling-law.com
dgermaine@sperling-law.com
ekelly@sperling-law.com
jbjork@sperling-law.com

John D. Radice (*pro hac vice* forthcoming)
Daniel Rubenstein (*pro hac vice* forthcoming)
Natasha Fernandez-Silber (*pro hac vice* forthcoming)
RADICE LAW FIRM, P.C.
475 Wall St.
Princeton, NJ 08540
Tel: (646) 245-8502
Fax: (609) 385-0745
jradice@radicelawfirm.com
drubenstein@radicelawfirm.com
nsilber@radicelawfirm.com

Attorneys for FWK Holdings LLC, Meijer, Inc., Meijer Distribution Inc., and the Proposed Class

CERTIFICATE OF SERVICE

I, Kristen A. Johnson, hereby certify that this document was served on all counsel of record via email on September 17, 2021 in accordance with the parties' Revised Joint Stipulation and [Proposed] Order Regarding Service, the Filing of the Plaintiffs' Consolidated Complaint, and Motion to Dismiss Briefing Schedule (ECF Nos. 26 and 5 in the above-captioned actions), as the Court's CM/ECF System was not available for filing on September 17, 2017 due to the NextGen system upgrade. The as-served document is now being filed, with one minor correction to remove inadvertent reference to Endo International plc as a defendant in the case captions, using the Court's CM/ECF system, which will automatically send a notification of such filing to all counsel of record via electronic mail.

Dated: September 20, 2021

/s/ Kristen A. Johnson
Kristen A. Johnson